EXHIBIT 3

Regulations On Supervision And Administration Of Medical Devices

Original Language Title: 医疗器械监督管理条例

People's Republic of China promulgated by Decree No. 650

On February 12, 2014 in the supervision and administration of medical devices Ordinance adopted amendments the 39th Executive meeting of the State Council, and will be revised after the promulgation of the regulations on supervision and administration of medical devices, as of June 1, 2014.

Prime Minister Li keqiang

March 7, 2014 regulations on supervision and administration of medical devices

(January 4, 2000 People's Republic of China promulgated by Decree No. 276, February 12, 2014 the 39th Executive meeting of the State Council amended by) Chapter I General provisions

First to ensure that the medical device is safe and effective, protection of human health and safety, this Ordinance is enacted.

Article in the People's Republic of China engaged in medical device development, production, distribution, use, activity, supervision and management should be subject to the regulations. Third State food and drug supervision and management is responsible for the national supervision and administration of medical devices.

Relevant departments under the State Council, within the scope of their respective duties is responsible for the supervision and administration of medical device-related work. Local people's Governments at or above the county level food and drug supervision and management is responsible for the administrative supervision and administration of medical devices.

Relevant departments of the local people's Governments at or above the county level shall, within their respective areas of responsibility are responsible for the supervision and administration of medical device-related work.

State food and drug supervision and Administration Department shall cooperate with the relevant departments of the State Council, implementing national medical device industry planning and policies.

Fourth national classification management of medical devices in accordance with the degree of risk.

First is the low level of risk, implementation of management can ensure safe and effective medical devices.

Second is with moderate risk, the need for strict control and management to ensure the safe and effective medical devices.

Is a high risk of the third kind, need to take special measures to strictly control and management to ensure their safe and effective medical devices.

Degree of risk evaluation of medical devices, medical devices should be considered the intended purpose, structure, methods of use, and other factors. State food and drug supervision and management is responsible for the development of medical device classification rules and categories, and according to the production, management and use of medical devices, medical devices in a timely manner of changes in risk analysis, evaluation, adjustments to the categories. Catalogue of the assessment and adjustment, should fully heed the medical device manufacturing enterprises as well as the views of users, industry organizations, with reference to the international classification of medical practice.

Categories of medical devices shall be announced to the public. Article fifth medical device development should follow safe, effective and economical principles.

State encourages research and innovation in medical devices, play the role of market mechanism, promote the popularization and application of medical device technologies, promote the development of medical device industry.

Article sixth medical device products shall comply with the mandatory national standard; there is no mandatory national standard, shall comply with the medical device mandatory industry standards. List of single-use medical devices by the food and drug supervision and administration departments of the State Council in conjunction with the health and family planning departments, adjusted and promulgated. Repeated use can guarantee safe and effective medical devices and are not included in the list of single-use medical devices.

Due to the design, production, sterilization techniques improved reuse can guarantee safe and effective medical devices, a list of single-use medical devices should be adjusted.

Seventh medical device industry organizations should strengthen industry self-regulation, advance the credit system construction, and urge enterprises to carry out production and business activities, and guide enterprises to be honest and trustworthy.

Chapter II medical device registration and filing

Article eighth class I medical device product management, class II and class III medical device product registration management.

Nineth class I medical device product filings and applications for class II and class III medical device product registration, shall submit the following information:

(A) risk analysis for product information;

(B) the product specification;

(C) the inspection reports;

(D) clinical evaluation of information;

(E) the product specification and labelling artwork;

(Vi) relating to product development, production and quality management system documentation;

(G) other information required to prove that products are safe and effective.

Medical device registration applicant, filing shall be responsible for the authenticity of the data. Article tenth class I medical device product record, location of the filing to the district people's Government municipal food and drug supervision and management departments to submit filings.

Among them, the product inspection report can be filed the self-test report clinical data do not include clinical trial reports, can be through literature, similar products clinical data shows that the medical device is safe and effective information.

Exports to China overseas manufacturers of class I medical devices, represented by its set up in our institution or corporation as an agent of the specified country, food and drug supervision and Management Department under the State Council to submit filings and filing in the country (region) authorities to allow the sale of medical devices documents.

Filings contained items change, should be changed to the original filing department record. Section 11th for class II medical devices product registration, registration applicant should be located, autonomous regions, or municipalities directly under the food and drug supervision and management departments registration information submitted.

Apply for a class III medical device product registration, registration applicant shall submit to the State

food and drug supervision and management application for registration information.

Exports to China the second class, overseas manufacturers of class III medical devices, should be established by the Chinese territory's representative bodies or specified China's domestic enterprises as agents, food and drug supervision and Management Department under the State Council submitted an application for registration information and applicant country (region) authorities to allow the sale of medical devices documents.

Class II and class III medical device product registration application information product inspection reports shall be issued by the inspection bodies of medical devices inspection reports; clinical evaluation report should include clinical trials, but in accordance with the provisions of this section 17th from except for clinical trials of medical devices. 12th accepts an application for registration of food and drug supervision and Administration Department shall accept applications for registration within 3 working days from the date of information referred to the technical review of authorities.

Technology evaluation agencies must complete technical reviews submitted to the food and drug administration review. 13th accepts an application for registration of food and drug supervision and Administration Department shall review the comments received within 20 business days from the date of decision.

To meet the requirements of safe, effective, registration and issue registration certificate of medical devices; do not meet the requirements, shall be rejected for registration and to state the reason in writing.

State food and drug supervision and management in the organization when the technical review on imported medical devices deemed necessary for the verification of the quality management system shall organize quality management system inspection agencies to carry out verification of the quality management system.

14th article has registered of second class, and third class medical devices products, its design, and raw materials, and production process, and applies range, and using method, occurred substantive changes, has may effect the medical devices security, and effective of, registered people should to original registered sector application handle change registered procedures; occurred non-substantive changes, not effect the medical devices security, and effective of, should will changes situation to original registered sector record. 15th medical instrument registration certificate is valid for 5 years.

Needs to extend the registration of the expiry, shall, before the expiry of 6 months lodge extension to the registration application for registration. Except as provided in the third paragraph of this article, a continuing registration applications received food and Drug Administration should be made before the expiry of the current registration certificate of medical devices the decision to approve the extension.

Fails to make a decision, considered to approve the extension.

Any of the following circumstances, refuse to continue registration:

(A) for applications for registration is not submitted within the deadline extended;

(B) medical device mandatory standards have been revised and renewal of registration of medical equipment could not meet the new requirements;

(C) for the treatment of rare diseases and respond to public health emergencies urgently needed medical equipment, is not completed within the prescribed time of medical device registration form containing the matters.

16th on new development has not been included in the category of medical devices, the applicant may, in accordance with the provisions of this Ordinance relating to the class III medical device product registration to apply directly for product registration, classification can be based on product categories and rules applying to the food and drug supervision and Management Department under the State Council category identified in accordance with the provisions of this Ordinance apply for registration or product record. Direct registration of applications for class III medical devices, food and drug supervision and Management Department under the State Council shall be determined according to the degree of risk categories, the registration of medical devices into categories.

Category recognized by the food and drug supervision and Management Department under the State Council shall, within 20 working days from the date of acceptance of the application to determine the category of medical devices and inform the applicant. 17th first class medical devices record and do not require clinical trials.

Application for class II and class III medical device product registration, clinical trials shall be conducted, however, any of the following circumstances, clinical trials from the:

(A) the clear mechanism, design, sophisticated production technology, with variety of clinical applications of medical devices already on the market for many years and no serious adverse events recorded, does not change the General purpose;

(Ii) non-clinical assessment can demonstrate that the medical device is safe and effective;

(C) the same varieties of medical device clinical trials or clinical use of analysis and evaluation of data obtained, can demonstrate that the medical device is safe and effective.

From the list of clinical trials of medical devices by the food and drug supervision and administration departments of the State Council formulated, adjusted and published. Article 18th medical device clinical trial, should be in accordance with the quality control of medical device clinical trials required, qualified clinical trial is carried out and submitted to the clinical trials according to location of provinces, autonomous regions, or municipalities directly under the food and drug supervision and Administration Department for the record.
Received food and Drug Administration for clinical trial record record briefing clinical trials should be place at the food and drug administration and Planning Department of public health.

Qualification conditions in institutions and medical device clinical trial clinical trial practice, by food and drug supervision and administration departments of the State Council in conjunction with the health and family planning formulated by the competent departments of the State Council and published in medical device clinical trials institutions by the State food and drug supervision and Administration Department in conjunction with the Planning Department of public health found and published. 19th class III medical device clinical trials on humans are at higher risk, should be approved by the State food and drug supervision and administration departments.

Clinical trials on humans are at higher risk of class III medical device listing by the State food and drug supervision and Administration Department, adjusted and promulgated. State food and Drug Administration approved clinical trials, intends to undertake clinical trials of medical devices should be body equipment, professional and other conditions, the risks of medical devices, clinical trials implementation, clinical benefit and risk analysis report for analysis.

Admission to clinical trials, should inform the paper as well as the place of clinical trials clinical trials of provinces, autonomous regions, or municipalities directly under the food and drug administration and Planning Department of public health.

Chapter III medical device production

20th medical equipment production activities, subject to the following conditions:

(A) fitting in with the production of medical devices production sites, environmental conditions, equipment, and professional and technical personnel;

(B) on production of quality control of medical devices agency or full-time inspectors and inspection equipment;

(C) ensure medical device quality management system;

(D) fitting in with the production of medical equipment service;

(E) the requirements set out in product development, production process.

21st engaged in production of class I medical devices from manufacturers to the local district people's Government municipal food and drug supervision and management departments and submitted to it in accordance with the conditions specified in section 20th supporting information.

22nd in class II and class III medical device production, production enterprises should be located, provinces, autonomous regions and municipalities apply for food and Drug Administration license and submit proof of the condition of the 20th article of the Ordinance have been met information and the production of medical devices in the registration form. Accepts an application for licensing of food and drug supervision and management departments should be within 30 working days from the date of receipt of application materials for the audit, according to the State food and drug supervision and management departments of medical device manufacturing practices requirements for verification.

To meet the required conditions, grant permission and issue medical device manufacturing license; does not meet the requirements of no permission and to state the reason in writing. Medical device manufacturing license is valid for 5 years.

Needs to extend the expiry, in accordance with the legal provisions concerning administrative license for continued clearance.

Article 23rd medical device manufacturing practices for medical device design and development, production equipment, purchase of raw materials, production process control, enterprise organization and staffing and other matters affecting the medical device is safe and effective to make specific provisions.

24th medical device manufacturing enterprises shall be in accordance with the requirements of medical device manufacturing practices, establish and perfect fitting in with the production of medical devices quality management system and ensure its effective operation strictly in accordance with the technical requirements of the registration or filing of products production, ensure medical devices manufactured comply with mandatory standards and technical requirements of the registration or filing of products.

Medical device manufacturing enterprise quality management system on a regular basis the functioning of self-examination, and to the local provinces, autonomous regions, or municipalities directly under the food and drug supervision and management departments to submit self reported.

25th medical device manufacturing enterprises in the production conditions change, no longer meets the requirements of medical device quality management system, manufacturers of medical devices shall immediately take the corrective measures that could affect the medical device is safe and effective, it shall immediately cease its operations, and to the local people's Governments at the county level report of the food and drug administration. 26th medical devices should use the common

name.

Generic names should be in compliance with the food and Drug Administration medical device developed by naming rules. 27th medical devices should have instructions, labels.

Contents of manuals, labels should be consistent with the relevant elements of the registration or filing.

Medical equipment manuals, labels shall indicate the following:

(A) the common name, model number, specifications;

(B) the name and address of the manufacturer and the address and contact information;

(C) the technical requirements of the product number;

(D) the date of production and the use of the term or expiry date;

(E) the product performance, structure, scope of application;

(F) the contraindications, precautions and other contents of the warning or prompt;

(G) installation and operating instructions or diagrams;

(H) maintenance and repair methods, special storage conditions, methods;

(I) the technical requirements shall be indicated in the additional content.

Class II and class III medical device should also be marked registration certificate number and the medical registrant's name, address and contact information.

Up to the consumer to use the safe use of medical devices should also have special instructions. 28th commissioned production of medical devices, commissioned by the client on the production of medical devices quality. Trustees should be in line with the provisions of this Ordinance, have the appropriate production conditions of medical device manufacturers.

Client shall strengthen the management of trustee practices, ensure production in accordance with statutory requirements.

Implantable medical device with high risk may not authorize specific directory formulated by the State food and drug supervision and Administration Department, adjusted and promulgated.

Fourth chapter medical device operation and use

29th medical equipment business, and scale and adapt to business premises and storage conditions, and adapt to and management of medical device quality management system and quality control agencies or personnel.

Article 30th of class II medical devices operation, from enterprises to the local district people's Government municipal food and drug supervision and management departments and submitted to it in accordance with the conditions specified in section 29th supporting information.

Article 31st class III medical device business, and trading enterprises shall, to the seat of the Municipal Government's food and drug supervision and management departments to apply for business license and submit supporting information eligible for article 29th of this Ordinance. Accept

business licenses applied for food and drug supervision and Administration Department shall review within 30 working days from the date of acceptance and, if necessary, organizations to verify.

To meet the required conditions, granting licenses and given a medical device license; does not meet the requirements of no permission and to state the reason in writing. Medical device license is valid for 5 years.

Needs to extend the expiry, in accordance with the legal provisions concerning administrative license for continued clearance. Article 32nd medical device distributing Enterprise purchased, and use of medical devices, shall examine the supplier's qualifications and certificates for medical devices and establish the raw materials purchase check record system.

Class II and class III medical device wholesale business as well as class III medical device retail business, sales record-keeping system should be established.

Records include:

(A) medical device name, model, specification, quantity;

(B) the batch number, expiry date, the date of sale of the medical device;

(C) the name of the manufacturer;

(D) the supply or purchase of the name, address and contact information;

(E) proof of license numbers. Raw materials purchase check record and sales records shall be true and in accordance with the provisions of the food and Drug Administration Department under the State Council retained the term.

Countries encourage the use of advanced technology to record them.

33rd transport, storage of medical equipment shall comply with medical instructions and label marking requirements; has special requirements for temperature, humidity and other environmental conditions, and shall take appropriate measures to ensure that medical device is safe and effective.

Article 34th medical devices unit should be commensurate with the variety and quantity of medical devices of the storage site and conditions.

Medical devices using units shall improve their technical training for staff, according to the product specification, technical operating specification requires the use of medical devices.

35th medical devices use a unit for reuse of medical devices, shall, according to the State Department of health family planning administrative departments of sterilization and management regulations for processing.

Single-use medical devices shall not be used, used should be in accordance with the relevant provisions of the State and destroyed records. 36th article medical devices using units on need regularly check, and test, and calibration, and maintenance, and maintenance of medical devices, should according to products manual of requirements for check, and test, and calibration, and maintenance, and maintenance and be records, timely for analysis, and assessment, ensure medical devices in good state, guarantees using quality; on using term long of large medical devices, should by Taiwan established using archives, records its using, and maintenance, and transfer, and actual using time, matters.

Record retention period shall not be less than 5 years after termination of medical devices require the use of the term.

37th medical device users should keep buying source for class III medical devices, and ensure information traceability.

Using a large medical device and Interventional medical devices and implants, medical devices should be the name, key technical parameters and other information, as well as closely related to using quality and safety record necessary information to medical records and other related records.

Article 38th found use of unsafe medical devices, medical devices shall immediately stop using, and notify the manufacturer or other bodies responsible for product quality maintenance; the overhaul has failed to achieve safety standards for medical devices, shall not continue to use it.

39th food and drug supervision and management departments and health family planning authorities in accordance with their respective responsibilities, respectively, using aspects of the medical device quality supervision management and use of medical devices.

40th medical device business, use the unit does not operate, use not legally registered, no certificate and expired, invalid or out of medical equipment.

41st transfer between medical devices used in medical devices, transferred by the transferring Party shall ensure that the medical device is safe and effective, shall not transfer expired, invalid, out and unqualified medical devices.
42nd article import medical devices should be in accordance with the provisions of chapter II of the present regulation is registered or documented medical devices.

Imported medical devices should have instructions in Chinese, Chinese labels. Manuals, labels shall satisfy the provisions of this Ordinance and related standard requirements, and instructions for medical devices set out in country of origin and the agent's name, address, and contact information.

Without Chinese instructions, labels or instructions, labels do not conform to the provisions of this article may not be imported.

Article 43rd entry-exit inspection and quarantine on imported medical devices inspection according to law; failed to pass the inspection must not be imported. Food and drug supervision and Management Department under the State Council shall promptly to inform the State administration for entry-exit inspection and Quarantine Bureau of import medical devices registration and filing.

Import port is located shall promptly to the local entry-exit inspection and quarantine agencies district municipal people's Government informed the food and Drug Administration clearance of imported medical devices.

44th export enterprises should ensure that their exports of medical devices medical devices comply with importing countries (regions) requirements.

45th medical device advertisement should be true and legal, shall not contain false, exaggerated, misleading content. Advertising of medical devices shall be subject to medical device manufacturers or import medical instruments Agent location of provinces, autonomous regions, or municipalities directly under the food and Drug Administration for examination and approval, approval from the advertising of medical devices and files. Publishers publish advertising of medical devices, shall first verify the approval document and authenticity of advertising; shall not be published without approval documents, approval documents of authenticity has not been verified or ad were inconsistent with the approval of medical device advertising.

The provinces, autonomous regions, or municipalities directly under the food and drug supervision and Administration Department shall publish and update the approved medical device advertising directory and approved advertising content.

People's Governments above provincial food and Drug Administration ordered a moratorium on the production, marketing, import and use of medical devices, released during the period of suspension shall not be involved in the advertising of medical devices.

Review of medical device advertising measures shall be formulated by the State food and drug supervision and management in conjunction with the industrial and commercial administrative departments.

The fifth chapter of adverse events and medical device recalls

46th national medical device adverse event monitoring system for medical device adverse event collection, analysis, evaluation and control.

47th medical apparatus production enterprise, and use should be produced by the operation or use of the medical device adverse event monitoring; found or suspected adverse events adverse events of medical devices shall be in accordance with the provisions of the food and drug administration departments of the State Council, reports to the medical device adverse event monitoring agency.

No units or individuals found or suspected adverse events adverse events of medical devices, the right to food and drug supervision and management departments or medical device adverse event monitoring agency reported.

48th State food and drug supervision and management departments should strengthen the construction of information network of medical device adverse event monitoring.

Medical device adverse event monitoring bodies should strengthen information on medical device adverse event monitoring initiative to collect information on adverse events; adverse events or adverse event report received, verification should be carried out promptly, investigation, analysis, assessment of adverse events, and to the food and drug administration and health and family planning department in charge of handling proposals.

Medical device adverse event monitoring agency shall publish contact information, facilitate the operation of medical equipment manufacturing enterprises, and use of medical device adverse events reported.

49th food and drug supervision and management departments should be based on medical device adverse event assessment warning issued in a timely manner the information and ordered a moratorium on the production, marketing, import and use of control measures.

People's Governments above provincial food and drug supervision and management departments should be in conjunction with the health and family planning department and relevant departments to cause sudden, mass grave injury or medical device adverse event death investigated and processed in a timely manner and similar medical instruments to strengthen the monitoring organization.

50th medical equipment production enterprises, and use of medical device adverse event monitoring should be technical bodies, the food and Drug Administration medical device adverse event investigation may be required.

51st under any of the following circumstances, people's Governments above provincial food and drug supervision and management departments should be on the registered organizations to carry out

evaluation of medical devices:

(A) according to the development of scientific research, the medical device is safe and effective cognitive changes;

(B) medical device adverse event monitoring, evaluation results indicate that there may be a defect of medical devices;

(C) the State food and drug supervision and Management Department under other circumstances that require re-evaluation. The evaluation results show that registered medical devices cannot be guaranteed safe, effective, and cancellation of registration certificate of medical devices by the original licensing departments, and to the public.

Cancellation of registration certificate of medical devices medical devices shall not manufacture, import, distribution, use,.

52nd article medical devices production enterprise found its production of medical devices not meet mandatory standard, and by registered or record of products technology requirements or exists other defects of, should immediately stop production, notification related production business enterprise, and using units and consumers stop business and using, recalled has listed sales of medical devices, take remedy, and destroyed, measures, records related situation, released related information, and will medical devices recalled and processing situation to food drug supervision management sector and health family planning competent sector report. Medical device distributing Enterprise found their medical circumstances set forth in the preceding paragraph, shall immediately cease business, notify the relevant production and operation of enterprises, and use, the consumer, and records may cease to operate and notifications.

Medical device manufacturing enterprise considers to be in accordance with the provisions of the preceding paragraph need to be recalled medical devices, should be immediately recalled.

Medical apparatus production enterprise fails to comply with the implementation of the provisions of this article recalls or stop operation, the food and Drug Administration may be ordered to recall or stop operating.

The sixth chapter the supervision and inspection

53rd of the food and Drug Administration for medical devices registration, record-keeping, manufacturing, distribution, use, activities to strengthen supervision and inspection, and focus on supervision and inspection on the following matters:

(A) medical device manufacturing enterprises in accordance with the registration or filing of the product technical requirements of production;

(B) whether the quality management system for medical device manufacturers maintain effective operation;

(C) whether the conditions of production and operation of the production and operation of medical devices comply with the statutory requirements.

54th in supervision and inspection, the food and Drug Administration has the following powers:

(A) entry field inspection, sampling;

(B) read, copy, attachment, seizure-related contracts, notes, account books and other relevant materials;

(C) the sealing up, distraining for medical devices does not comply with the statutory requirements, and used spare parts, raw materials, and tools for illegal production of medical devices and equipment;

(D) seizure in violation of the regulations provide for the medical equipment production and business activities of the site.

Food and drug supervision and Administration Department conduct supervision and inspection, shall produce their documents, keep the business secrets of the units inspected.

Units and individuals should be on supporting the supervision and inspection of the food and drug administration, not withholding the information.

55th on the human body caused by injury or evidence that may be harmful to human health and medical equipment, food and drug supervision and management departments can take a moratorium on the production, import, distribution, use of emergency control measures. Food and drug supervision and management departments should strengthen the article 56th medical device manufacturing enterprises and using units of production, management and use of medical device inspection.

Inspection inspection fees and any other fees shall not be charged, incorporate the Government's budget requirements.

People's Governments above provincial food and drug supervision and management departments should be based on inspection findings released in a timely manner medical device quality announcement. 57th medical device inspection agency accreditation in accordance with relevant regulations of the State exercises unified management.

Certification and accreditation administration departments of the State Council in conjunction with the food and Drug Administration authorized inspection agencies, can be applied to medical equipment to carry out the inspection.

Food and Drug Administration medical device needs to be tested in law enforcement, shall entrust a qualified medical device inspection agencies, and pay the associated costs. Party disagrees with the conclusion, he may, within 7 working days from the date of receipt of the inspection findings have right to have medical device inspection institutions select qualified. Responsibility should review medical device inspection institutions at the State food and drug supervision and management departments to review conclusions within the stipulated time.

Review the conclusions for final conclusions. 58th article on may exists harmful material or unauthorized change medical devices design, and raw materials and production process coexist in security hidden of medical devices, according to medical devices national standards, and industry standard provides of test project and test method cannot test of, medical devices test institutions can added test project and test method for test; using added test project, and test method obtained of test conclusion, by State food drug supervision management sector approved,

Can be used as a food and Drug Administration medical device quality basis.

59th district of municipal and County Food and drug supervision and management departments should strengthen supervision and inspection of medical device advertising; found, alter approved ad content without approval of medical device advertising, should be to the local provinces, autonomous regions and municipalities report of the food and drug administration, who announced to the public. Industrial and commercial administrative departments shall, in accordance with the control of

advertising laws, administrative laws and regulations, supervision and inspection of medical equipment, investigate and deal with violations.

Food and Drug Administration found that medical device advertising illegal publication, it shall submit a transfer location to process the recommendation and in accordance with the relevant industrial and commercial administrative departments at the same level. 60th State food and drug supervision and management departments to establish a unified information platform for the supervision and administration of medical devices. Food and drug supervision and management departments should be made public through timely information platform in accordance with medical device license, filing, inspection, violations investigated and dealt with day-to-day supervision and management of information.

However, not divulging business secrets.
Food and drug supervision and administration of medical device registration and record people, production and operation of enterprises, and use established credit records, to increase supervision and inspection frequency with a poor credit record.

61st food and drug supervision and management departments should publicize the unit's contact information, counselling, complaints, he added. Food and drug supervision and management departments receiving and consulting related to the supervision and administration of medical devices, shall promptly reply complaints or information, shall promptly verify, process and reply.

For inquiries, complaints, reporting and response, verification, processing and should be recorded, saved.

About medical equipment development, production, operation, use of substantiated report acts of investigation, the food and drug supervision and management departments of whistleblower shall be rewarded.

62nd article formulated by the State food and drug supervision and administration departments, adjust and modify the list of regulations and norms relating to the supervision and administration of medical devices, shall be made public for comment; take the form of hearings, feasibility study meeting, listen to the experts, and the production and operation of medical devices unit, consumer views, and related organizations.

The seventh chapter legal liability 63rd article has following case one of of, by County above government food drug supervision management sector confiscated illegal proceeds, and illegal production business of medical devices and for illegal production business of tool, and equipment, and raw materials, items; illegal production business of medical devices goods value amount insufficient 10,000 yuan of, and at 50,000 yuan above 100,000 yuan following fine; goods value amount 10,000 yuan above of, and at goods value amount 10 times times above 20 times times following fine; plot serious of,

Within 5 years will not be accepted relevant responsible persons and firms ' medical device license application:

(A) production, management has not obtained the registration certificate of medical devices of type II and class III medical devices;

(B) without the permission of class II and class III medical device production;

(C) unauthorized operation of class III medical devices.

Preceding paragraph of the first case, the circumstances are serious, medical device manufacturing license issuing Department revoked licence or a medical device license.

64th provide false information or other deceptive means to obtain medical registration certificate, medical device production license, business license, advertising approval documents permit, has been made by the original certificate revoked by the Department of permits and fines of between 50,000 yuan and 100,000 yuan, within 5 years will not be accepted persons responsible for licensing of medical devices and enterprise applications.

Forged, and variable made, and sale, and rental, and lending related medical devices license documents of, by original sent card sector be collection or revoked, confiscated illegal proceeds; illegal proceeds insufficient 10,000 yuan of, at 10,000 yuan above 30,000 yuan following fine; illegal proceeds 10,000 yuan above of, at illegal proceeds 3 times times above 5 times times following fine; constitute violation security management behavior of, by police organ law be security management punishment.

65th had not been filed in accordance with this Ordinance, the Government's food and drug supervision and administration departments at or above the county level shall order correction within; it fails to society announcements not filing units and product name, may be fined a maximum of 10,000 yuan.

Providing false information when filing, by the Government's food and drug supervision and administration departments at or above the county level to announce the filing unit and product name are serious, persons directly responsible for 5 years not to engage in medical device manufacturing operations. 66th article has following case one of of, by County above government food drug supervision management sector ordered corrected, confiscated illegal production, and business or using of medical devices; illegal production, and business or using of medical devices goods value amount insufficient 10,000 yuan of, and at 20,000 yuan above 50,000 yuan following fine; goods value amount 10,000 yuan above of, and at goods value amount 5 times times above 10 times times following fine; plot serious of, ordered discontinued closed, until by original sent card sector revoked medical devices registered card, and

Medical device production license, business license:

(A) the production, distribution, use, did not meet mandatory standards or does not comply with the registration or filing of product technical requirements of the medical devices;

(B) medical device manufacturers are not in accordance with the registration or filing of the product technical requirements for production, or not in accordance with the provisions of this Ordinance to establish and maintain the effective operation of the quality management system;

(C) management, use of certificates, expired, invalid or out of medical equipment, or use of medical devices that are not legally registered;

(D) the food and Drug Administration to order in accordance with the provisions of this Ordinance recall or stop managing, still refuses to recall or stop operation of medical devices;

(E) the delegate does not have the conditions specified in the present regulations of enterprises producing medical devices, or not on the entrusted management of production.

67th article has any of the following circumstances, the people's Governments above the county level food and drug regulatory agency ordered corrective action and fines of between 10,000 yuan and 30,000 yuan; the circumstances are serious, shall be ordered to suspend production until revoked by the original licensing department medical device manufacturing license, medical device license:

(A) the manufacturer of medical devices production conditions change, no longer meet the medical

devices quality management system requirements, no rectification in accordance with the provisions of this Ordinance, to stop production, reports;

(B) production, operating instructions, labels for medical devices does not comply with the provisions of this Ordinance;

(C) is not in accordance with the medical device instructions and label marking requirements of transportation and storage of medical devices;

(D) the transfer expires, the expiration, eliminated or unqualified use of medical devices.

68th under any of the following circumstances, the people's Governments above the county level food and drug supervision and management departments and shall be ordered to correct health family planning authorities in accordance with their respective responsibilities and give a warning; it refuses to, more than 5000 Yuan and fined a maximum of 20,000 yuan; the circumstances are serious, shall be ordered to suspend production until revoked by the original licensing department medical device manufacturing license, medical device license:

(A) medical device manufacturers is not submitted in accordance with the requirements of quality management system of self-examination report;

(B) the medical equipment business, and use is not in accordance with these regulations provide for the establishment and implementation of the raw materials purchase check record system of medical devices;

(Iii) class II and class III medical device wholesale business as well as class III medical device retail business enterprises is not in accordance with these regulations provide for the establishment and implementation of sales record-keeping systems;

(D) for reusable medical devices, medical instruments disinfection and use not in accordance with the management regulations for processing;

(E) medical devices using the reuse of single-use medical devices, or failing to destroy used disposable medical instruments;

(Vi) requires periodic inspection, testing, calibration and maintenance of medical equipment, medical equipment and use not in accordance with product specifications inspection, testing, calibration, maintenance, and record, analyses, assessments in a timely manner to ensure that medical devices are in good condition;

(G) medical devices the use of units purchased were not properly saved a third class medical sources, or not in accordance with the provisions of medical devices and implants and Interventional medical devices of related records with the information recorded in the medical record;

(VIII) medical devices using units discovery of unsafe medical devices does not immediately stop using, notifications, maintenance, or to continue to use the overhaul still can not meet the safety standards of medical devices;

(I) the medical device manufacturing enterprises, and use not in accordance with the provisions of this regulation for medical device adverse event monitoring, not in accordance with the requirements for reporting adverse events, or for medical device adverse event monitoring agency, food and Drug Administration adverse event investigation fails to cooperate. 69th article violation this Ordinance provides carried out medical devices clinical test of, by County above government food drug supervision management sector ordered corrected or immediately stop clinical test, can at 50,000

yuan following fine; caused serious consequences of, law on directly is responsible for of competent personnel and other directly responsibility personnel give downgraded, and dismissed or fired of disposition; has medical devices clinical test institutions qualification of, by grant its qualification of competent sector revoked medical devices clinical test institutions qualification,

Do not handle accreditation applications within 5 years.

Medical devices clinical test institutions issued false report of, by grant its qualification of competent sector revoked medical devices clinical test institutions qualification, 10 years within not accepted its qualification finds application; by County above government food drug supervision management sector at 50,000 yuan above 100,000 yuan following fine; has illegal proceeds of, confiscated illegal proceeds; on directly is responsible for of competent personnel and other directly responsibility personnel, law give dismissed or fired of disposition.

70th article medical devices test institutions issued false test report of, by grant its qualification of competent sector revoked test qualification, 10 years within not accepted its qualification finds application; at 50,000 yuan above 100,000 yuan following fine; has illegal proceeds of, confiscated illegal proceeds; on directly is responsible for of competent personnel and other directly responsibility personnel, law give dismissed or fired of disposition; by fired disposition of, since disposition decided made of day up 10 years within shall not engaged in medical devices test work.

71st in violation of the provisions of this Ordinance, publish advertising of medical devices not approved file, without first verifying document authenticity that publish advertising of medical devices, or advertising content inconsistent with the approval of medical device advertising, managed by the administration of industry and commerce in accordance with the relevant advertising laws and administrative regulations shall be punished.

Tampering with approved medical device advertising content from original issuing authorities to revoke the approval document of the advertising of medical devices, do not handle advertising approval applications within 2 years.

Publication of false advertising of medical devices, by the people's Governments above provincial food and Drug Administration decided to suspend sales of the medical device and to the public; sales of the medical device, government food and drug supervision and administration departments at or above the county level shall confiscate the illegal sales of medical devices, and fined a maximum of between 50,000 yuan and 20,000 yuan.

72nd article medical devices technology review institutions, and medical devices bad event monitoring technology institutions not in accordance with this Ordinance provides perform duties, led review, and monitoring work appeared major errors of, by County above government food drug supervision management sector ordered corrected, informed criticism, give warning; caused serious consequences of, on directly is responsible for of competent personnel and other directly responsibility personnel, law give downgraded, and dismissed or fired of disposition.
73rd food and drug supervision and management departments and their staff should be strictly in accordance with this regulation the penalties set forth in type and magnitude, according to the nature of the offence and the circumstances exercise of the right of administrative punishment, and the specific measures formulated by the State food and drug supervision and Administration Department.

74th article violation this Ordinance provides, County above government food drug supervision management sector or other about sector not perform medical devices supervision management duties or abuse, and negligence, and engages in of, by monitored organ or appointment organ on directly is responsible for of competent personnel and other directly responsibility personnel law give warning, and demerit or remember than of disposition; caused serious consequences of, give downgraded, and dismissed or fired of disposition.

75th in violation of these regulations, constitutes a crime, criminal responsibility shall be investigated according to law; personal, property or other damage shall bear liability.

The eighth chapter by-laws

76th article of the Ordinance the meaning of the following terms:

Medical devices, is refers to directly or indirect for human of instrument, and equipment, and apparatus, and body outside diagnosis reagents and the calibration real, and material and other similar or related of items, including by need of computer software; its utility main through physical, way get, not through pharmacological learn, and Immunology or metabolism of way get, or although has these way participation but only up auxiliary role; its purpose is:

(A) the disease diagnosis, prevention, monitoring, treatment or alleviation of;

(B) injury diagnosis, monitoring, treatment, alleviation or compensation;

(C) the physiological structure or physiological process or inspection, replacement and adjustment support;

(D) life support or maintenance;

(E) the control of pregnancy;

(Vi) through to examine samples from the body, for the purpose of medical or diagnostic information.

Medical device use, refers to the use of medical institutions providing medical services to others, including medical license to practice medical institutions, access to family planning technical service institutions license to practice family planning technical service institutions, as well as the law does not need to obtain a medical license to practice blood, Apheresis plasma, rehabilitation, assistive devices fit body. 77th medical device product registration fee can be charged.

Specific projects, respectively by the State Council Finance, pricing departments in accordance with the relevant provisions of the State.

78th non-profit contraceptive management of medical devices, as well as medical and health institutions to respond to public health emergencies and the development of the management of medical devices, from food and drug supervision and administration departments of the State Council in conjunction with the health and family planning formulated by the competent departments of the State Council.

Medical equipment management of traditional Chinese medicine, by the food and drug supervision and administration departments of the State Council in conjunction with the Chinese medicine sector pursuant to the provisions of this Ordinance; scope of rehabilitation assistive devices class I medical devices and its management, by the food and drug supervision and administration departments of the State Council in conjunction with the Home Department pursuant to the provisions of this Ordinance.

79th army supervision and administration of medical devices using, by the army health authorities according to the provisions of this Ordinance and the relevant military organizations. 80th article of the regulations come into force on June 1, 2014. a

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EXHIBIT 4

2014 China Law LEXIS 2345

Reporter
2014 China Law LEXIS 2345 *

Title: Regulations on the Supervision and Administration over Medical Devices (Revised in 2014)

Document Number: 2346710

Article Number: Order of the State Council of the People's Republic of China No.650

Topic: Medical Treatment & Health Law

Effective: Revised

Promulgator: State Council

Promulgation Date: 03-07-2014

Effective Date: 06-01-2014

Effect Area: [*1] National

Source: China Online

Update: replacement

Regulations on the Supervision and Administration over Medical Devices (Revised in 2014)

Order of the State Council of the People's Republic of China No.650

March 7, 2014

The Regulations on the Supervision and Administration over Medical Devices, which were revised and adopted at the 39th executive meeting of the State Council on February 12, 2014, are hereby promulgated and shall come into force as of June 1, 2014.

Premier: Li Keqiang

Regulations on the Supervision and Administration over Medical Devices

(promulgated under the Order of the State Council of the People's Republic of China No.276 on January 4, 2000 and revised and adopted at the 39th executive meeting of the State Council on February 12, 2014)

Chapter I General Provisions

Article 1 The Regulations on the Supervision and Administration over Medical Devices (hereinafter referred to as the "Regulations") are hereby formulated for the purposes of ensuring the safety and effectiveness of medical devices and guaranteeing the human health and safety of lives.

Article 2 For the research and development, production, operation or use of, and supervision and administration [*2] over medical devices within the territory of the People's Republic of China, the Regulations shall be observed.

Article 3 The food and drug supervision and administration department under the State Council shall be responsible for the supervision and administration over medical devices throughout the country. The relevant departments of the State Council shall be responsible for the supervision and administration related to medical devices within their respective scope of duties.

The food and drug supervision and administration departments of the local people's governments at county level or above shall be responsible for the supervision and administration over medical devices within their respective administrative regions. The relevant departments of the local people's governments at county level or above shall be responsible for the supervision and administration related to medical devices within their respective scope of duties.

The food and drug supervision and administration department under the State Council shall coordinate with the relevant departments of the State Council in implementing the national industrial plans and policies on medical devices.

Article 4 The [*3] state adopts classified administration over medical devices by risk level.

Class I medical devices shall refer to those devices with low risk whose safety and effectiveness can be guaranteed through routine administration.

Class II medical devices shall refer to those devices with moderate risk whose safety and effectiveness should be ensured by strict control and administration.

Class III medical devices shall refer to those devices with relatively high risk whose safety and effectiveness should be ensured by taking special measures to conduct strict control and administration.

When the risk level of medical devices is assessed, such factors as desired purpose, structural feature and usage of medical devices shall be taken into consideration.

The food and drug supervision and administration department under the State Council shall be responsible for working out classification rules and classification contents of medical devices and timely analyze and assess, according to the production, operation and use of medical devices, the change in risk of medical devices and then adjust the classification contents. When formulating and adjusting the classification contents, the food and [*4] drug supervision and administration department under the State Council shall fully listen to the opinions of producing and operating

enterprises, users and industrial organization of medical devices and refer to the international practices for classification of medical devices. Classification contents of medical devices shall be disclosed to the public.

Article 5 The research and development of medical devices shall follow the principles of safety, effectiveness and saving. The state encourages the research and innovation of new medical devices, gives full play of the role of market mechanism and drives the promotion and application of new technology of medical devices and to promote the development of medical device industry.

Article 6 Medical devices shall comply with the compulsory national standards for medical devices; where no compulsory national standards are provided, the compulsory industrial standards for medical devices shall be complied with.

Disposable classification contents shall be prepared, adjusted and published by the food and drug supervision and administration department under the State Council in concert with the competent health and family planning department [*5] of the State Council. Reusable medical devices whose safety and effectiveness can be ensured shall not fall into the scope of the disposable classification contents. For the reusable medical devices whose safety and effectiveness can be ensured after the improvement of design, production process and sterilization and disinfection technology shall be moved out of the disposable classification contents.

Article 7 Industrial organizations of medical devices shall strengthen industry self-regulation, promote the construction of credit system, urge the enterprise to legally conduct the production and operation activities and instruct the enterprises to be honest and trustworthy.

Chapter II Registration and Filing of Medical Devices

Article 8 For Class I medical devices, the products filing management is implemented while for Class II and Class III ones, the products registration management is implemented.

Article 9 For filing of Class I medical devices and application for registration of Class II and Class III medical devices, the following materials shall be submitted:

1. materials for analysis of product risks;
2. technical requirements for products;
3. products inspection [*6] report;
4. clinical assessment materials;
5. products specification and label sample;
6. quality management system documents related to the research and production of products; and
7. other materials necessary for proving the safety and effectiveness of products.

The applicant for registration or filing of medical devices shall be responsible for the authenticity of materials submitted.

(Relevant articles: Legislation 1)

Article 10 In case of filing for Class I medical devices, the applicant for filing shall submit to the food and drug supervision and administration departments of the people's governments of the cities divided into districts where the applicant for filing is located the filing materials, in which the products inspection report may be the self-inspection report; clinical assessment materials exclude

the clinical trial report but may be the materials proved to be safe and effective by data obtained through documents and clinical use of the similar products.

For overseas producing enterprises who export Class I medical devices to China, it is representative institutions set up by such producing enterprises in China or enterprise legal persons in China designated [*7] by such producing enterprises who act as agents that shall submit to the food and drug supervision and administration departments under the State Council the filing materials and supporting documents that the competent departments in the country (region) where the applicant for filing is located allow the listing for sales of such medical devices.

Where there is any change in matters stipulated in the filing materials, the filing for change shall be made with the original filing department.

Article 11 In case of the application for registration of Class II medical devices, the applicant for registration shall submit to the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where the applicant for registration is located the registration application materials. In case of the application for registration of Class III medical devices, the applicant for registration shall submit to the food and drug supervision and administration departments under the State Council the registration application materials.

For overseas producing enterprises who export Class II and [*8] Class III medical devices to China, it is representative institutions set up by such producing enterprises in China or enterprise legal persons in China designated by such producing enterprises who act as agents that shall submit to the food and drug supervision and administration department under the State Council the registration application materials and supporting documents that the competent departments in the country (region) where the applicant for registration is located allow the listing for sales of such medical devices.

The products inspection reports in the registration application materials for Class II and Class III medical devices shall be the inspection report issued by the medical device inspection institutions; clinical assessment materials shall include the clinical trial reports with the exception of those for medical devices which are exempt from clinical trial in accordance with the provisions of Article 17 hereof.

Article 12 The food and drug supervision and administration department that accepts the registration application shall, within three working days after its acceptance, transfer the registration application materials to technical evaluation institutions, [*9] who shall, after the completion of technical evaluation, submit its evaluation opinions to the food and drug supervision and administration department.

Article 13 The food and drug supervision and administration department that accepts the registration application shall, within 20 working days after receipt of evaluation opinions, make a decision. For the medical devices that meet the requirements of safety and effectiveness, the registration shall be approved and a medical device registration certificate shall be granted; for the medical devices that fail to meet such requirements, the registration shall be refused and written reasons shall be given.

Where the food and drug supervision and administration department under the State Council thinks it necessary to check the quality management system when organizing the technical evaluation on imported medical devices, it shall organize the technical institutions for inspection on quality management system to check the quality management system.

Article 14 For registered Class II and Class III medical devices, where any substantial change in their design, raw materials, production process, applicable scope and usage may affect [*10] the safety and effectiveness of such medical devices, the registrant shall apply to the original registration department for handling procedures for change of registration; where any non-substantial change does not affect the safety and effectiveness of such medical devices, the registrant shall report the change to the original registration department for filing.

Article 15 The medical device registration certificate is valid for five years. Where the period of validity for the registration needs to be extended upon the expiration, an application for such extension shall be made to the original registration department six months before the expiration.

Except for the circumstances stipulated in Paragraph 3 of this Article, the food and drug supervision and administration department that receives the application for extending the registration shall make the decision to approve the extending before the expiration of the medical device registration certificate. If the decision fails to be made within the time limit, it is deemed as an approval.

Extension for registration shall not be approved under any of the following circumstances:

1. the registrant fails to apply for extending [*11] the registration within the specific time limit;

2. where the compulsory standards for medical devices have been revised, and the medical devices applied for extending the registration cannot meet the new requirements; and

3. for medical devices in urgent demand used for treating rare diseases and responding to emergent public health events, the matters stipulated in the medical device registration certificate fail to be finished within the specific time limit.

Article 16 In case of medical devices newly developed but not included in the classification contents, the applicant may directly apply for product registration in accordance with the provisions on product registration for Class III medical devices hereof and also may determine the class of products according to the classification rules and apply for registration or make filing in accordance with the provisions hereof after applying to the food and drug supervision and administration department under the State Council for confirmation of the class.

In case of medical devices that directly applied for product registration for Class III medical devices, the food and drug supervision and administration department under the [*12] State Council shall, according to the risk level, determine their class and then timely include in the classification contents the medical devices whose registration is approved. Where the class confirmation is applied for, the food and drug supervision and administration department under the State Council shall, within 20 working days after accepting the application, determine the class of the medical devices and inform the applicant of the result.

Article 17 For product filing for Class I medical devices, no clinical trial is needed. While for application for the product registration for Class II and Class III medical devices, a clinical trial shall be made. However, a clinical trial may be exempt under any of the following circumstances:

1. the medical devices have clear working mechanism, established design and mature production process and the same kind of medical devices that have been listed have been used for many years without material bad records and change of general purpose thereof;

2. the medical devices are proved to be safe and effective through non-clinical evaluation; and

3. the medical devices are proved to be safe and effective through analysis and evaluation [*13] on the data obtained from the clinical trial or clinical use of the same kind of medical devices.

The contents of medical devices exempt from clinical trial shall be formulated, adjusted and promulgated by the food and drug supervision and administration department under the State Council.

Article 18 Clinical trial of medical devices shall be carried out by the eligible clinical trial institutions according to the requirements of quality management standards for clinical trial of medical devices and shall be filed with the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where the applicant for clinical trial is located. The food and drug supervision and administration department that accepts the filing for clinical trial shall report the filing to the food and drug supervision and administration department at the same level and health and family planning department where the clinical trial institution is located.

The qualification identification conditions for clinical trial institutions of medical devices and quality management standards for clinical trial [*14] shall be formulated and promulgated by the food and drug supervision and administration department under the State Council in concert with the health and family planning department of the State Council; the clinical trial institutions for medical devices shall be identified and promulgated by the food and drug supervision and administration department under the State Council in concert with the health and family planning department of the State Council.

Article 19 Where the clinical trial of Class III medical devices poses high risk to human beings, it shall be approved by the food and drug supervision and administration department under the State Council. The contents for Class III medical devices with high risk to human beings shall be formulated, adjusted and promulgated by the food and drug supervision and administration department under the State Council.

When approving the clinical trial, the food and drug supervision and administration department under the State Council shall conduct comprehensive analysis on the equipment, professionals and other conditions of the institutions proposing to undertake the clinical trial of medical devices and the risk level of medical devices, [*15] implementation scheme for clinical trial and analysis report for comparison of clinical benefit and risk. The approval of the clinical trial shall be reported to the food and drug supervision and administration department and the health and family planning department of the people's government in the province, autonomous region or municipality directly under the Central Government where the applicant for clinical trial and clinical trial institutions are located.

Chapter III Production of Medical Devices

Article 20 To engage in the production of medical devices, the producing enterprise shall meet the following requirements:

1. having the production place, environmental conditions, production equipment and professional technicians that meet the needs of the medical devices to be produced;

2. having the institutions or professionals and the inspection equipment for the quality inspection of the medical devices to be produced;

3. having management system to ensure the quality of medical devices;

4. having after-sale service that meet the needs of the medical devices to be produced; and

5. requirements provided for in documents on product development and production process.

[*16]

Article 21 Where engaging in production of Class I medical devices, the producing enterprise shall make a filing with the food and drug supervision and administration department of the people's government of the city divided into districts where the producing enterprise is located and submit the supporting materials that meet the requirements of Article 20 hereof.

Article 22 Where engaging in production of Class II and Class III medical devices, the producing enterprise shall apply to the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where the producing enterprise is located for production license and submit the supporting materials that meet the requirements of Article 20 hereof as well as the registration certificates for the medical devices produced.

The food and drug supervision and administration department that accepts the application for production license shall, within 30 working days after its acceptance shall review the application materials and check them according to the requirements set forth in quality management standards for production [*17] of medical devices formulated by the food and drug supervision and administration department under the State Council. For the medical devices that meet the conditions stipulated, the license shall be approved and a medical device production license shall be granted; for the medical devices that fail to meet such conditions, the license shall be refused and written reasons shall be given.

The medical device production license is valid for five years. Where the period of validity for the license needs to be extended upon the expiration, the procedures for such extension shall be handled in accordance with the provisions of laws related to administrative licensing.

Article 23 The quality management standards for production of medical devices shall provide specific provisions on such matters that affect the safety and effectiveness of medical devices as the design and development, conditions for production equipment, purchasing of raw materials, control of production process of medical devices as well as institutional setup and personnel allocation of the enterprise.

Article 24 A producing enterprise of medical devices shall, according to the requirements of the quality management [*18] standards for production of medical devices, set up and improve the quality management system that meets the needs of the medical devices produced and ensure the effective operation thereof; it shall, in strict accordance with the registered and filed technical requirements for products, organize the production to ensure that the manufactured medical devices comply with the compulsory standards and the registered and filed technical requirements for products.

The producing enterprise of medical devices shall regularly inspect the operation of the quality management system by itself and submit its self-inspection report to the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where the producing enterprise is located.

Article 25 Where any change in the production conditions of a producing enterprise of medical devices leads to failure to meet the requirements of the quality management system for medical devices, the producing enterprise shall immediately adopt rectification measures; where such change may affect the safety and effectiveness of medical devices, [*19] the producing enterprise shall immediately stop its production and report to the food and drug supervision and administration department of the people's government at county level where the producing enterprise is located.

Article 26 Medical devices shall use general names, which shall comply with the naming rules for medical devices formulated by the food and drug supervision and administration department under the State Council.

Article 27 Medical devices shall be attached with instructions and labels whose contents shall be consistent with those registered and filed.

The instructions and labels of medical devices shall state the following matters:

1. general name, model and specification;
2. name, domicile, production address and contact information of the producing enterprise;
3. serial number of the technical requirements for products;
4. production date and service life or expiration date;
5. product performance, main structure and applicable scope;
6. contraindications, points for attention and other contents necessary to be warned or reminded;
7. installation and operation instructions or drawings;
8. maintenance method and special storage condition and method; [*20] and
9. other contents that shall be stated as required by the technical requirements for products.

For Class II and Class III medical devices, No. of the medical device registration certificate and the name, address and contact information of the registrant of the medical devices shall be also stated.

For the medical devices used by the consumers independently, special instructions for safe use shall be also stated.

Article 28 For the medical devices produced by entrust, the entrusting party shall be responsible for the quality of entrusted medical devices. The entrusted shall be the medical device producing enterprise that complies with the provisions hereof and has corresponding production conditions. The entrusting party shall strengthen the management over the production by the entrusted to ensure the production is conducted according to statutory requirements.

The implantable medical devices with high risk shall not be entrusted to be produced. The specific contents shall be formulated, adjusted and promulgated by the food and drug supervision and administration department under the State Council.

Chapter IV Operation and Use of Medical Devices

Article 29 To engage [*21] in the operation of medical devices, an operating enterprise shall have the business site and storage conditions that can meet the needs of business scale and scope and quality management system and shall be equipped with quality management institutions or personnel that can meet the needs of the operated medical devices.

Article 30 Where engaging in operation of Class II medical devices, an operating enterprise shall make a filing with the food and drug supervision and administration department of the people's government of the city divided into districts where the operating enterprise is located and submit the supporting materials that meet the requirements of Article 29 hereof.

Article 31 Where engaging in operation of Class III medical devices, an operating enterprise shall apply to the food and drug supervision and administration department of the people's government of

the city divided into districts where the operating enterprise is located for business license and submit the supporting materials that meet the requirements of Article 29 hereof.

The food and drug supervision and administration department that accepts the application for operation license shall, within [*22] 30 working days after its acceptance, review the application materials and organize an examination if necessary. For the medical devices that meet the conditions stipulated, the license shall be approved and a medical device operation license shall be granted; for the medical devices that fail to meet such conditions, the license shall be refused and written reasons shall be given.

The medical device operation license is valid for five years. Where the period of validity for the license needs to be extended upon the expiration, the procedures for such extension shall be handled in accordance with the provisions of laws related to administrative licensing.

Article 32 When the operating enterprises of medical devices or users purchase medical devices, they shall check the qualification of suppliers and the eligible supporting materials of medical devices and establish an entry inspection record system. The operating enterprises engaging in wholesale business of Class II and Class III medical devices and retail business of Class III medical devices shall establish a sales record system.

Matters to be recorded include:

1. name, mode, specification and quantity of medical devices;

[*23] 2. batch number, period of validity and sales date of medical devices;

3. name of the producing enterprise;

4. name, address and contact information of their supplier or purchaser; and

5. numbers of supporting documents of relevant license, etc.

The entry inspection record and sales record shall be real and be kept during the period specified by the food and drug supervision and administration department under the State Council. The state encourages the record by means of advanced technology.

Article 33 The transportation and storage of medical devices shall comply with the requirements of instructions and labels of medical devices; if there are special requirements on temperature, humidity and other environmental conditions, corresponding measures shall be taken to ensure the safety and effectiveness of medical devices.

Article 34 The users of medical devices shall have storage place and conditions that meet the needs of the varieties and quantities of medical devices.

The users of medical devices shall strengthen the technical training of the personnel and use the medical devices according to the requirements of product specification and technical operation standards.

[*24]

Article 35 The reused medical devices shall be handled by the users of medical devices in accordance with the provisions on sterilization and management stipulated by the competent health and family planning department of the State Council.

The disposable medical devices shall not be reused and the used ones shall be destroyed and recorded in accordance with the relevant provisions of the state.

Article 36 The users of medical devices shall, according to the requirements of product instructions, check, inspect, calibrate and maintain the medical devices that regularly need doing so and make records, timely analysis and evaluation to make sure the medical devices are in a good condition and to guarantee the quality in use; for large medical devices with long use life, files for use of such medical devices shall be established one by one and such matters as use, maintenance, transfer and actual use life shall be recorded. The retention period for records shall be no less than five years after the expiration of specified use life of medical devices.

Article 37 The users of medical devices shall carefully keep the source information of Class III medical devices purchased and [*25] ensure the traceability of such information.

Where large medical devices and implantable and interventional medical devices are used, such information as name and key technical parameters of medical devices and essential information closely related to quality and safety for use shall be recorded in medical history and other relevant records.

Article 38 Where any medical device in use is found to have potential safety hazards, the users of medical devices shall immediately stop to use it and require the producing enterprise or other institutions responsible for product quality to conduct examination and maintenance; if the medical device fails to meet the safety standards for use after the examination and maintenance, it shall no longer be used.

Article 39 The food and drug supervision and administration department and the competent health and family planning department shall exercise their respective duties to supervise and administer the quality and use of medical devices in use.

Article 40 The operating enterprise and user of medical devices shall not operate and use the expired, invalid and obsolete medical devices without eligible supporting materials that fail to be [*26] registered in accordance with the law.

Article 41 For transfer of medical devices in use between the users of medical devices, the transferor shall ensure the safety and effectiveness of the medical devices transferred and no expired, invalid, obsolete and unqualified medical devices shall be transferred.

Article 42 Imported medical devices shall be those registered or filed in accordance with the provisions of Chapter II hereof.

Imported medical devices shall be attached with Chinese instructions and Chinese labels, which shall comply with the provisions hereof and requirements of the relevant compulsory standards. The instructions shall clearly state the origin of medical devices and name, address and contact information of the agent. Medical devices without Chinese instructions and Chinese labels or those whose instructions and labels do not comply with the provisions of this Article shall not be imported.

Article 43 Entry-exit inspection and quarantine institutions shall carry out inspection on imported medical devices in accordance with the law; where the medical devices are unqualified, they shall not be imported.

The food and drug supervision and administration department [*27] under the State Council shall timely report to the national entry-exit inspection and quarantine department the registration and

filing of imported medical devices. The entry-exit inspection and quarantine institutions where the import port is located shall timely report to the food and drug supervision and administration department of the people's government of the city divided into districts where the import port is located the customs clearance of imported medical devices.

Article 44 An exporter of medical devices shall make sure that its imported medical devices meet the requirements of the importing country (region).

Article 45 The advertisement of medical devices shall be real and legal and shall not include false, exaggerate and misleading contents.

Advertisement of medical devices shall be examined and approved by the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where the producing enterprise or the agent of imported medical devices is located. Approval documents for such advertisement shall be obtained. Where the advertiser publishes the advertisement [*28] of medical devices, it shall check the approval documents and the authenticity thereof in advance; no advertisement of medical devices with approval documents not obtained, authenticity thereof not proved or contents inconsistent with approval documents shall be published. The food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government shall disclose and timely update the advertisement list of approved medical devices and approved advertising contents.

Where the food and drug supervision and administration department of the people's government at provincial level or above orders to suspend the production, sales, importing and use of the medical devices, no such medical devices shall be advertised during the period of suspension.

The examination measures for advertisement of medical devices shall be prepared by the food and drug supervision and administration department under the State Council in concert with the administrative department for industry and commerce under the State Council.

Chapter V Handling of Adverse Events and Recall of Medical Devices

Article 46 [*29] The state shall set up monitoring system for adverse events of medical devices to timely collect, analyze, evaluate and control such adverse events.

Article 47 The producing and operating enterprise or users shall monitor the adverse events of medical devices produced, operated or used by them; if any adverse event or suspicious event of medical devices is found, it shall be reported to the monitoring technical institutions of adverse events of medical devices in accordance with the provisions of the food and drug supervision and administration department under the State Council.

Any unit and individual who finds any adverse event or suspicious event of medical devices is entitled to report to the food and drug supervision and administration department or the monitoring technical institutions of adverse events of medical devices.

Article 48 The food and drug supervision and administration department under the State Council shall strengthen the construction of monitoring information network for adverse events of medical devices.

The monitoring technical institutions of adverse events of medical devices shall intensify the monitoring of adverse events of medical devices and [*30] actively collect the information of

adverse events; if any adverse event is found or reported, the monitoring technical institutions shall timely check, investigate, analyze and evaluate the adverse event and propose to the food and drug supervision and administration department and the competent health and family planning department with handling suggestions.

The monitoring technical institutions of adverse events of medical devices shall make its contact information public for the convenience of reporting the adverse events of medical devices by the producing and operating enterprises or users.

Article 49 The food and drug supervision and administration department shall, according to the evaluation results of adverse events of medical devices, take such control measures as publishing warning information and ordering to suspend the production, sales, importing and use in a timely manner.

The food and drug supervision and administration department of the people's government at provincial level or above shall, in concert with the competent health and family planning department and the relevant departments at the same level, organize a timely investigation on and deal with the adverse [*31] events of medical devices resulting in sudden serious damage or death, or serious damage to or death of masses, and strengthen the monitoring on the medical devices of the same kind.

Article 50 The producing and operating enterprise or users shall be cooperative in investigation of adverse events of medical devices carried out by the monitoring technical institutions of adverse events of medical devices and the food and drug supervision and administration department.

Article 51 The food and drug supervision and administration department of the people's government at provincial level or above shall reevaluate the registered and filed medical devices under any of the following circumstances:

1. there is any change in recognition of safety and effectiveness of medical devices with the development of scientific research;

2. the results of monitoring and evaluation of adverse events of medical devices state that the medical devices may have defects; and

3. other circumstances necessary for reevaluation stipulated by the food and drug supervision and administration department under the State Council.

Where the results of reevaluation suggest that safety and effectiveness of the [*32] registered medical devices cannot be guaranteed, the medical device registration certificate shall be cancelled by the original issuing department and such cancellation shall be published to the public. The medical devices with medical device registration certificate cancelled shall not be produced, imported, operated or used.

Article 52 Where a producing enterprise of medical devices finds that the medical devices produced by it do not meet the compulsory standards or registered or filed technical requirements for products or exist other defects, it shall immediately stop the production and require the relevant producing and operating enterprises, users and consumers to stop to operate and use such medical devices, recall the medical devices already sold on the market, take remedial measures or destroy such defective devices, record the relevant situation and release the relevant information, and report to the food and drug supervision and administration department and the competent health and family planning department the recall and handling of medical devices.

Where an operating enterprise of medical devices finds that the medical devices operated by it fall into any circumstance [*33] stated in the preceding paragraph, it shall immediately stop the operation, inform the relevant producing and operating enterprises, users and consumers and make the relevant records. Where the producing enterprise of medical devices thinks such devices fall into the category of those necessary for recall in accordance with the provisions of the preceding paragraph, such devices shall be immediately recalled.

Where a producing and operating enterprise fails to recall the medical devices or suspend its operation in accordance with the provisions of this Article, the food and drug supervision and administration department may order it to recall the medical devices or suspend its operation.

Chapter VI Supervision and Examination

Article 53 The food and drug supervision and administration department shall strengthen the supervision and examination on the registration, filing, production, operation and use, and focus the supervision and examination on the following matters:

1. whether the producing enterprise of medical devices organizes the production according to the registered or filed technical requirements for products;

2. whether the quality management system of the producing [*34] enterprise of medical devices keeps effective operation; and

3. whether the producing and operating conditions of the producing and operating enterprises of medical devices consistently meet the statutory requirements.

Article 54 During the supervision and examination, the food and drug supervision and administration department is entitled to:

1. conduct an inspection and a sampling on the site;

2. look up, copy, seal up or detain the relevant contracts, notes, account books and other relevant materials;

3. seal up or detain the medical devices that fail to meet the statutory requirements, illegally used spare and accessory parts and raw materials, and tools and equipment for illegally producing medical devices; and

4. seal up the places for production and operation of the medical devices in violation of the provisions hereof.

Where the food and drug supervision and administration department carries out supervision and examination, it shall show its law enforcement certificate and keep confidential of trade secrets of the examined unit.

The relevant units and individuals shall be cooperative in the supervision and examination by the food and drug supervision and administration [*35] department and shall not conceal any relevant issue.

Article 55 For medical devices that are harmful to human beings or are proved to probably jeopardize the health of human beings, the food and drug supervision and administration department may take urgent control measures as suspending production, importing, operation and use.

Article 56 The food and drug supervision and administration department shall reinforce the random inspection over the medical devices produced, operated and used by the producing and operating

enterprises and users. No inspection fees or other expenses shall be charged for the random inspection and the expenses required shall be included in the budget of government at the same level.

The food and drug supervision and administration department of the people's government at provincial level or above shall, according to the results of random inspection, publish the announcement of quality of medical devices in a timely manner.

Article 57 Qualification identification by the medical device inspection institutions implements unified management in accordance with the relevant provisions of the state. Only the supervision and administration department certificated [*36] and recognized by the State Council may, in concert with the food and drug supervision and administration department under the State Council, inspect the medical devices.

Where the food and drug supervision and administration department needs to inspect the medical devices during the law enforcement, it shall entrust qualified medical device inspection institutions to do so and pay the relevant expenses.

Where the party concerned has any objection to the inspection conclusion, it may, within seven working days after receipt of it, select a qualified medical device inspection institution to re-inspect the devices. Such medical device inspection institution that conducts the reinspection shall provide a conclusion within the time limit stipulated by the food and drug supervision and administration department under the State Council. The conclusion of the reinspection shall be final.

Article 58 Where the medical devices that probably have hazardous substances or whose deign, raw materials and production process are changed without authorization and that have potential safety hazards cannot be inspected through inspection items and inspection methods specified in the national standards [*37] and industrial standards for medical devices, the medical device inspection institution may supplement inspection items and inspection methods to conduct the inspection; The inspection conclusion acquired by use of supplementary inspection items and inspection methods shall, upon approval of the food and drug supervision and administration department under the State Council, be the basis for identification of quality of medical devices by the food and drug supervision and administration department.

Article 59 The food and drug supervision and administration department of the people's government of the city divided into districts and at county level shall enhance the supervision and examination on the advertisement of medical devices; if finding any advertisement of medical devices that is disapproved or whose contents approved are falsified, it shall report to the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where it is located, and make such advertisement public.

The administrative department for industry and commerce shall, in accordance with the provisions [*38] of relevant laws and administrative regulations on administration over advertisements, supervise and examine the advertisement of medical devices and punish illegal acts. If the food and drug supervision and administration department finds any illegal release of advertisement of medical devices, it shall propose the handling suggestions and transfer the case according to the relevant procedures to the administrative department for industry and commerce at the same level where it is located.

Article 60 The food and drug supervision and administration department under the State Council shall establish a unified supervision and administration information platform for medical devices. The food and drug supervision and administration department shall timely disclose such daily supervision and administration information as license, filing, random inspection and punishment of illegal acts of medical devices on the information platform, but shall not reveal the trade secrets of the party concerned.

The food and drug supervision and administration department shall set up credit archives for registrants, filing persons of medical devices, producing and operating enterprises and users and [*39] conduct more supervision and examination on those with bad credit records.

Article 61 The food and drug supervision and administration department and other departments shall make public their contact information and accept the consultations, complaints and reporting. When the food and drug supervision and administration department and other departments are consulted on supervision and administration of medical devices, they shall give a reply in a timely manner; if receiving a complaint and reporting, they shall check and handle the complaint and reporting and give a reply in a timely manner. The information on consultations, complaints and reporting as well as the reply, check and handling shall be recorded and kept.

Where the reporting on research, production, operation and use of medical devices is investigated to be true, the food and drug supervision and administration department and other departments shall give an award to reporters.

Article 62 When the food and drug supervision and administration department under the State Council formulates, adjusts and revises the contents specified herein and specifications related to the supervision and administration over medical [*40] devices, it shall seek for public comments, and it shall, by means of hearing and discussion meetings or otherwise, listen to the opinions of experts, producing and operating enterprises and users of medical devices, consumers and the relevant organizations.

Chapter VII Legal Liabilities

Article 63 Under any of the following circumstances, the food and drug supervision and administration department of the people's government at county level or above shall confiscate illegal gains, the illegally produced and operated medical devices and tools, equipment, raw materials and other articles used for illegal production and operation; where the value of illegally produced and operated medical devices is less than CNY10,000, a fine of not less than CNY50,000 but not more than CNY100,000 shall be imposed; where the value is not less than CNY10,000, a fine of not less than ten times but not more than 20 times the value shall be imposed; where the circumstances are serious, the application for license of medical devices proposed by the relevant persons responsible and enterprises shall not be accepted within five years:

1. the enterprise produces and operates Class II and Class III medical [*41] devices without obtaining the medical device registration certificate;

2. the enterprise engages in the production of Class II and Class III medical devices without permission; and

3. the enterprise engages in the operation of Class III medical devices without permission.

Where the circumstance of Item 1 of the preceding paragraph occurs and the circumstance is serious, the original issuing department shall revoke the medical device production license or the medical device operation license.

Article 64 In case the medical device registration certificate, medical device production license, medical device operation license, advertisement approval documents and other licenses have been obtained by providing false materials or by other means of fraudulence, the original issuing department shall revoke the licenses obtained and impose a fine of not less than CNY50,000 but not more than CNY100,000, and the application for license of medical devices proposed by the relevant persons responsible and enterprises shall not be accepted within five years.

In case the relevant medical device licenses are counterfeited, altered, traded, leased or lent, the original issuing department shall [*42] confiscate or revoke such licenses and confiscate illegal gains; in case the illegal gains are less than CNY10,000, a fine of not less than CNY10,000 but not more than CNY30,000 shall be imposed; in case the illegal gains are not less than CNY10,000, a fine of not less than three times but not more than five times the illegal gains shall be imposed; in case a violation of security administration is constituted, the public security organs shall impose a security administration punishment in accordance with the law.

(Relevant articles: Legislation 1)

Article 65 Where a filing fails to be made in accordance with the Regulations, the food and drug supervision and administration departments of the local people's governments at county level or above shall order to make corrections within the time limit; if corrections are not made within the time limit, the unit and names of products failing to be filed shall be made public and a fine of not more than CNY10,000 shall be imposed.

Where false materials are provided in filing, the food and drug supervision and administration departments of the local people's governments at county level or above shall make public the unit and names of products [*43] to be filed; if the circumstance is serious, the person directly responsible shall not engage in the production and operation of medical devices with five years.

(Relevant articles: Legislation 1)

Article 66 Under any of the following circumstances, the food and drug supervision and administration department of the people's government at county level or above shall order to make corrections, confiscate the illegally produced, operated or used medical devices; where the value of illegally produced, operated or used medical devices is less than CNY10,000, a fine of not less than CNY20,000 but not more than CNY50,000 shall be imposed; where the value is not less than CNY10,000, a fine of not less than five times but not more than ten times the value shall be imposed; where the circumstances are serious, the food and drug supervision and administration department of the people's government at county level or above shall order to stop the production and operation and the original issuing department shall revoke the medical device registration certificate, medical device production license and medical device operation license:

1. the enterprise produces, operates or uses medical devices [*44] that do not comply with the compulsory standards or the registered or filed technical requirements for products;

2. the producing enterprise of medical devices fails to organize the production according to the registered or filed technical requirements for products; or to establish quality management system and keep effective operation in accordance with the provisions hereof;

3. the enterprise operates and uses the expired, invalid and obsolete medical devices without eligible supporting materials or uses those failing to be registered in accordance with the law;

4. the enterprise refuses to recall medical devices or stop the operation of medical devices after the food and drug supervision and administration department order it to recall medical devices or stop the operation of medical devices in accordance with the provisions hereof; and

5. the enterprise entrusts other enterprises without the conditions specified herein to produce medical devices or fails to manage the production by the entrusted.

Article 67 Under any of the following circumstances, the food and drug supervision and administration department of the people's government at county level or above shall order [*45] to make corrections and impose a fine of not less than CNY10,000 but not more than CNY30,000; where the circumstances are serious, the food and drug supervision and administration department of the people's government at county level or above shall order to stop the production and operation and the original issuing department shall revoke the medical device production license and medical device operation license:

1. production conditions of the producing enterprise of medical devices have been changed and thus no longer meet the requirements of quality management system for medical devices but the producing enterprise fails to rectify the conditions and to stop the production and reporting in accordance with the Regulations;

2. production and operation instructions and labels do not comply with those for medical devices specified herein;

3. the enterprise fails to transport and store the medical devices according to the requirements of instructions and labels thereof; and

4. the enterprise transfers the expired, invalid, obsolete and unqualified medical devices in use.

Article 68 Under any of the following circumstances, the food and drug supervision and administration department [*46] and health and family planning department of the people's government at county level or above shall, according to their respective duties, order to make corrections and give a warning; where the enterprise refuses to make corrections, then a fine of not less than CNY5,000 but not more than CNY20,000 shall be imposed; where the circumstances are serious, the food and drug supervision and administration department and health and family planning department of the people's government at county level or above shall order to stop the production and operation and the original issuing department shall revoke the medical device production license and medical device operation license:

1. the producing enterprise of medical devices fails to submit the quality management system self-inspection report;

2. the operating enterprise and user of medical devices fail to establish and implement the entry inspection record system for medical devices in accordance with the provisions hereof;

3. the operating enterprise engaging in wholesale business of Class II and Class III medical devices and retail business of Class III medical devices fails to establish and implement the sales record system in [*47] accordance with the provisions hereof;

4. the user of medical devices fails to handle the reused medical devices in accordance with the provisions on sterilization and administration;

5. the user of medical devices reuses the disposable medical devices or fails to destroy the disposable medical devices that have been used in accordance with the provisions;

6. for medical devices that need regular check, inspection, calibration and maintenance, the user of medical devices fails to do so according to the requirements of the product instructions and to make records, timely analysis and evaluation so as to make sure the medical devices are in a good condition;

7. the user of medical devices fails to carefully keep the source materials of Class III medical devices purchased or fails to record the information on large medical devices and implantable and interventional medical devices in the medical history and other relevant records;

8. the user of medical devices that has found medical devices with potential safety hazards does not stop the use or ask for maintenance or continues to use the medical devices that are repaired but are not up to the safety use standards; and

9. the producing [*48] and operating enterprise and user of medical devices fail to monitor the adverse events of medical devices in accordance with the provisions hereof and to report the adverse events as required, or are not cooperative in investigation on the adverse events by the monitoring technical institutions of adverse events of medical devices and the food and drug supervision and administration department.

Article 69 Where the enterprise organizes clinical trial of medical devices in violation of the Regulations, the food and drug supervision and administration department of the people's government at county level or above shall order to make corrections or to immediately stop the clinical trial and may impose a fine of not more than CNY50,000; where a serious consequence is caused, such punishments as degradation, dismissal or discharge shall be imposed upon the directly responsible person and other persons directly responsible; where the enterprise has qualifications for clinical trial institutions of medical devices, the competent department that grants such qualifications shall cancel the qualifications and shall not accept the application for qualification identification within five [*49] years.

Where the clinical trial institutions of medical devices issue false reports, the competent department that grants their qualifications for clinical trial institutions of medical devices shall cancel the qualifications and shall not accept the application for qualification identification within ten years; the food and drug supervision and administration department of the people's government at county level or above shall impose a fine of not less than CNY50,000 but not more than CNY100,000; illegal gains, if any, shall be confiscated; such punishments as dismissal or discharge shall be imposed upon the directly responsible person and other persons directly responsible.

Article 70 Where the inspection institutions of medical devices issue false inspection reports, the competent department that grants such qualifications shall cancel the inspection qualifications and shall not accept the application for qualification identification within ten years; a fine of not less than CNY50,000 but not more than CNY100,000 shall be imposed; illegal gains, if any, shall be confiscated; such punishments as dismissal or discharge shall be imposed upon the directly responsible person and [*50] other persons directly responsible; where the punishment of discharge is imposed, the inspection institutions shall not engage in the inspection of medical devices within ten years as of the date of such punishment.

Article 71 In violation of the provisions hereof, where the enterprise publishes the advertisement of medical devices whose approval documents are not obtained, publishes the advertisement of medical devices without proving the authenticity of the approval documents in advance or publishes the advertisement whose contents published are inconsistent with the approval documents, the administrative department for industry and commerce shall impose punishments in accordance with the provisions of the laws and administrative regulations on advertisement management.

Where the enterprise falsifies the contents of approved advertisement of medical devices, the original issuing department shall cancel the approval documents of such medical devices and shall not accept its applications for approval of advertisements within two years.

Where the enterprise publishes false advertisement of medical devices, the food and drug supervision and administration department of the people's [*51] government at county level or above shall decide to stop the sales of such medical devices and make it public; where the enterprise

still sells such medical devices, the food and drug supervision and administration department of the people's government at county level or above shall confiscate the illegally sold medical devices and impose a fine of not less than CNY20,000 but not more than CNY50,000.

Article 72 Where technical evaluation institutions of medical devices and monitoring technical institutions of adverse events of medical devices, who fail to perform their duties in accordance with the provisions hereof, make major mistakes in the process of evaluation and monitoring, the food and drug supervision and administration department of the people's government at county level or above shall order them to make corrections, circulate a note of criticism and give a warning; where serious consequences have been caused, such punishments as degradation, dismissal or discharge shall be imposed on the directly responsible person and other persons directly responsible in accordance with the law.

Article 73 The food and drug supervision and administration department and the staff [*52] thereof shall, in strict accordance with the types and range of punishments specified herein and according to the nature of violations and specific circumstances, exercise the power of administrative penalty. Specific measures shall be formulated by the food and drug supervision and administration department under the State Council.

Article 74 In violation of the provisions hereof, the food and drug supervision and administration department of the people's government at county level or above or other relevant departments do not perform their duties of supervision and administration over medical devices or misuse their authority, neglect their duties or practice graft, the supervision organ or the department in charge of appointment and removal shall give a warning, record a demerit or record a serious demerit on the directly responsible person and other persons directly responsible; where serious consequences have been caused, such punishments as degradation, dismissal or discharge shall be imposed in accordance with the law.

Article 75 In violation of the provisions hereof, where a crime has been constituted, criminal liability shall be pursued in accordance with the law; where [*53] any damage to person or property or other damages have been caused, the compensation liabilities shall be assumed in accordance with the law.

Chapter VIII Supplementary Provisions

Article 76 Definitions of the following terms herein:

Medical devices refer to instruments, equipment, appliances, in-vitro diagnostic reagents and calibrators, materials as well as other similar or relevant articles, including necessary computer software; the utility of medical devices is mainly achieved by physical or other means instead of by means of pharmacology, immunology or metabolism or by such means but only acting as auxiliary functions, the purposes of which are as follows:

1. diagnose, prevention, monitoring, treatment or relief on diseases;

2. diagnose, monitoring, treatment, relief or functional compensation on injury;

3. inspection on, substitution for, adjustment to or support of physical structures or physical process;

4. support or maintenance of life;

5. control of pregnancy; and
6. inspection on sample of human body to provide information for medical treatment or diagnosis.

The user of medical devices refers to the institutions that use medical devices to provide medical [*54] treatment and other technical services, including the medical institutions that have obtained the Practicing License of Medical Institutions, family planning technical service institutions that have obtained the Practicing License of Family Planning Technical Service Institutions and blood stations, blood plasma stations and assistive product adaption institutions that do not need to have Practicing License of Medical Institutions.

Article 77 Fees for registration of medical devices may be charged. Specific charging items and standards shall be worked out respectively by the competent financial and pricing departments under the State Council in accordance with relevant provisions of the state.

Article 78 Administrative measures for non-profit contraceptive medical devices and administrative measures of medical sanitation institutions for medical devices researched to response to public health emergencies shall be prepared by the food and drug supervision and administration department under the State Council in concert with the competent health and family planning department of the State Council.

Administrative measures for traditional Chinese medical devices shall be prepared [*55] by the food and drug supervision and administration department under the State Council in concert with the traditional Chinese medicine administration department under the State Council in accordance with the relevant provisions hereof; the scope of assistive medical devices and administrative measures thereof shall be prepared by the food and drug supervision and administration department under the State Council in concert with the civil administration department under the State Council in accordance with the provisions hereof.

Article 79 The supervision and administration over use of military medical devices shall be organized and implemented by the competent military health department in accordance with the Regulations and the relevant military provisions.

Article 80 The Regulations shall come into force as of June 1, 2014.

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EXHIBIT 5

2017 China Law LEXIS 694

Reporter
2017 China Law LEXIS 694 *

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Regulations on Supervision and Administration of Medical Devices (Revised in 2017)

Order of the State Council of the People's Republic of China No.680

May 4, 2017

(Promulgated by the Order of the State Council of the People's Republic of China No.276 on January 4, 2000; revised and adopted at the 39th executive meeting of the State Council on February 12, 2014; and revised by the Decision of the State Council on Revising the Regulations on the Supervision and Administration of Medical Devices on May 4, 2017)

Chapter I General Provisions

Article 1 The Regulations on the Supervision and Administration over Medical Devices (hereinafter referred to as the "Regulations") are hereby formulated for the purposes of ensuring the safety and effectiveness of medical devices and guaranteeing the human health and safety of lives.

Article 2 Activities in terms of development, manufacture, operation and utility as well as supervision and administration of medical devices within the territory of China shall be subject to these Regulations.

Article 3 The food and drug supervision and administration department under the State Council shall be responsible for the [*2] supervision and administration of medical devices throughout the country. The relevant departments of the State Council shall be responsible for the supervision and administration related to medical devices within their scope of duties respectively.

The food and drug supervision and administration departments of the local people's governments at county level or above shall be responsible for the supervision and administration of medical devices within their respective administrative regions. The relevant departments of the local people's governments at county level or above shall be responsible for the supervision and administration related to medical devices within their respective scope of duties.

The food and drug supervision and administration department under the State Council shall coordinate with the relevant departments of the State Council in implementing the national industrial plans and policies on medical devices.

Article 4 The State adopts classified administration of medical devices by risk level.

Class I medical devices with low risk, whose safety and effectiveness can be guaranteed through routine administration.

Class II medical devices with medium risk, whose safety [*3] and effectiveness can be ensured by strict control and administration.

Class III medical devices with high risk, whose safety and effectiveness can be ensured by strict control and administration through special measures.

To evaluate the risk level of a medical device, expected purpose, structural features, method of application and other factors thereof shall be considered.

The food and drug supervision and administration department under the State Council shall be responsible for working out classification rules and contents of classified medical devices, and timely analyze and assess, according to the production, operation and use of medical devices, the change in risk of medical devices and then adjust the classification contents. When formulating and adjusting the classification contents, the food and drug supervision and administration department under the State Council shall fully listen to the opinions of producing and operating enterprises, users and industrial organization of medical devices and refer to the international practices for classification of medical devices. Classification contents of medical devices shall be disclosed to the public.

Article 5 The research [*4] and development of medical devices shall follow the principles of safety, effectiveness and conservation. The state encourages the research and innovation of new medical devices, gives full play of the role of market mechanism, drives the promotion and application of new technology of medical devices, to promote the development of medical device industry.

Article 6 Medical devices shall comply with the compulsory national standards for medical devices; where no compulsory national standards are provided, the compulsory industrial standards for medical devices shall be complied with.

Contents of disposable medical devices shall be prepared, adjusted and published by the food and drug supervision and administration department under the State Council in concert with the competent health and family planning department of the State Council. Reusable medical devices whose safety and effectiveness can be ensured shall not fall into the disposable contents. For the reusable medical devices whose safety and effectiveness can be ensured after the improvement of design, production process and sterilization and disinfection technology shall be moved out of the disposable classification contents.

[*5]

Article 7 Industrial organizations of medical devices shall strengthen industry self-regulation, promote the construction of credit system, urge enterprises to legally conduct production and operation activities and instruct the enterprises to be honest and trustworthy.

Chapter II Registration and Record-filing of Medical Devices

Article 8 For Class I medical devices, the record-filing management shall be implemented, while for Class II and Class III ones, the registration management shall be implemented.

Article 9 For record-filing of Class I medical devices and application for registration of Class II and Class III medical devices, the following materials shall be submitted:

1. materials for analysis of product risks;
2. technical requirements for products;
3. products inspection report;
4. clinical assessment materials;
5. products specification and label sample;
6. quality management system documents related to the research and production of products; and
7. other materials necessary for proving the safety and effectiveness of products.

The applicant for registration or filing of medical devices shall be responsible for the authenticity of materials submitted.

Article [*6] 10 In the case of the record-filing for Class I medical devices, an applicant shall submit the filing materials to the food and drug supervision and administration departments of the people's governments of the cities divided into districts where the applicant is located. The products inspection report contained in the record-filing materials may be the self-inspection report; clinical assessment materials exclude the clinical trial report but may be the materials proved to be safe and effective by data obtained through documents and clinical use of the similar products.

For overseas manufacturers who export Class I medical devices to China, it is the representative institutions set up by such manufacturers in China or the enterprise legal persons in China designated by such manufacturers who act as agents that shall submit to the food and drug supervision and administration departments under the State Council the filing materials and supporting documents that the competent departments in the country (region) where the applicant for filing is located allow the listing for sales of such medical devices.

Where there is any change in matters stipulated in the filing materials, the filing [*7] for change shall be made with the original filing department.

Article 11 In the case of the application for Class II medical devices registration, the applicant shall submit the registration application materials to the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where the applicant is located. In the case of the application for registration of Class III medical devices, the applicant for registration shall submit the registration application materials to the food and drug supervision and administration departments under the State Council.

For overseas manufacturers who export Class II and Class III medical devices to China, it is representative institutions set up by such manufacturers in China or enterprise legal persons in China designated by such manufacturers as agents that shall submit to the food and drug supervision and administration department under the State Council the registration application materials and supporting documents in which the local competent departments in the country (region) allow such medical devices to be marketed.

The product [*8] inspection reports in the registration application materials for Class II and Class III medical devices shall be the inspection reports issued by the medical device inspection institutions; clinical assessment materials shall include the clinical trial reports with the exception of those for medical devices which are exempt from clinical trial in accordance with the provisions of Article 17 hereof.

Article 12 The food and drug supervision and administration department that accepts the registration application shall, within three working days after its acceptance, transfer the registration application materials to technical evaluation institutions, who shall, upon the completion of technical evaluation, submit its evaluation opinions to the food and drug supervision and administration department.

Article 13 The food and drug supervision and administration department that accepts the registration application shall make a decision within 20 working days after receipt of evaluation opinions. For the medical devices that meet the requirements of safety and effectiveness, the registration shall be approved and a medical device registration certificate shall be granted; for the medical [*9] devices that fail to meet such requirements, the registration shall be refused and written reasons shall be given.

Where the food and drug supervision and administration department under the State Council finds it necessary to check the quality management system when organizing the technical evaluation on imported medical devices, it shall organize the technical inspection institutions of the quality management system to check the quality management system.

Article 14 For registered Class II and Class III medical devices, where any substantial change in their design, raw materials, production process, applicable scope and usage has potential impact on the

safety and effectiveness of such medical devices, the registrant shall apply to the original registration department for handling procedures for change of registration; where any non-substantial change does not affect the safety and effectiveness of such medical devices, the registrant shall report the change to the original registration department for record-filing.

Article 15 The medical device registration certificate is valid for five years. Where the period of validity therefor needs to be extended upon the expiration, an [*10] application for such extension shall be made to the original registration department six months before the expiration.

Except for the circumstances stipulated in Paragraph 3 hereof, the food and drug supervision and administration department that receives the application shall make the decision to approve the extending before the expiration of the medical device registration certificate. If the decision fails to be made within the time limit, it is deemed as an approval.

An application for registration renewal shall not be approved under any of the following circumstances:

1. the registrant fails to apply for extending the registration within the specific time limit;

2. where the compulsory standards for medical devices have been revised, and the medical devices applied for extending the registration cannot meet the new requirements; and

3. for medical devices in urgent demand used for treating rare diseases and responding to emergent public health events, the matters stipulated in the medical device registration certificate fail to be finished within the specific time limit.

Article 16 In the case of medical devices newly developed but not included in the classification contents, [*11] an applicant may directly apply for product registration in accordance with the provisions on product registration for Class III medical devices hereof and also may determine the class of products according to the classification rules and apply for registration or make record-filing in accordance with the provisions hereof after applying to the food and drug supervision and administration department under the State Council for confirmation of the class.

In the case of medical devices that directly applied for product registration for Class III medical devices, the food and drug supervision and administration department under the State Council shall, according to the risk level, determine their class and then timely include in the classification contents the medical devices whose registration is approved. Where the class confirmation is applied for, the food and drug supervision and administration department under the State Council shall, within 20 working days after accepting the application, determine the class of the medical devices and inform the applicant of the result.

Article 17 For product filing for Class I medical devices, no clinical trial is needed. While for application [*12] for the product registration for Class II and Class III medical devices, a clinical trial shall be made. However, a clinical trial may be exempt under any of the following circumstances:

1. the medical devices have clear working mechanism, established design and mature production process and the same kind of medical devices that have been listed have been used for many years without material bad records and change of general purpose thereof;

2. the medical devices are proved to be safe and effective through non-clinical evaluation; and

3. the medical devices are proved to be safe and effective through analysis and evaluation on the data obtained from the clinical trial or clinical use of the same kind of medical devices.

The contents of medical devices exempt from clinical trial shall be formulated, adjusted and promulgated by the food and drug supervision and administration department under the State Council.

Article 18 Clinical trials for medical devices shall, according to the requirements of quality management standards on clinical trials for medical devices, be carried out in the qualified clinical trial institutions and, be record-filed with the food and drug supervision [*13] and administration departments of the people's government in the province, autonomous region or municipality directly under the Central Government where the entity requesting for clinical trials is located. The food and drug supervision and administration department that accepts the record-filing for clinical trials shall report the record-filing to the food and drug supervision and administration department and health and family planning department at the same level of the place where the clinical trial institution is located.

Medical devices clinical trial institutions perform the record-filing management. Conditions that shall be met, as well as the record-filing management measures and quality management standards on clinical trials for medical devices clinical trial institutions, shall be formulated and promulgated by the food and drug supervision and administration department of the State Council in concert with the health and family planning department of the State Council.

Article 19 Where the clinical trial of Class III medical devices poses high risk to human beings, it shall be approved by the food and drug supervision and administration department under the State Council. [*14] The contents for Class III medical devices with high risk to human beings shall be formulated, adjusted and promulgated by the food and drug supervision and administration department under the State Council.

When reviewing the clinical trial, the food and drug supervision and administration department under the State Council shall conduct comprehensive analysis of the equipment, professionals and other conditions of the institutions proposing to undertake the clinical trial of medical devices and the risk level of medical devices, implementation scheme for clinical trial and analysis report for comparison of clinical benefit and risk. The approval of the clinical trial shall be reported to the food and drug supervision and administration department and the health and family planning department of the people's government in the province, autonomous region or municipality directly under the Central Government where the applicant for clinical trial and clinical trial institutions are located.

Chapter III Production of Medical Devices

Article 20 To engage in the production of medical devices, the enterprise concerned shall meet the following requirements:

1. having the production [*15] place, environmental conditions, production equipment and professional technicians that meet the needs of the medical devices to be produced;

2. having the institutions or professionals and the inspection equipment for the quality inspection of the medical devices to be produced;

3. having management system to ensure the quality of medical devices;

4. having after-sale service that meet the needs of the medical devices to be produced; and
5. requirements provided for in documents on product development and production process.

Article 21 Where engaging in production of Class I medical devices, the producing enterprise shall make a record-filing with the food and drug supervision and administration department of the people's government of the city divided into districts where the producing enterprise is located and submit the supporting materials that meet the requirements of Article 20 hereof.

Article 22 Where engaging in production of Class II and Class III medical devices, the producing enterprise shall apply to the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government [*16] where the producing enterprise is located for production license and submit the supporting materials that meet the requirements of Article 20 hereof as well as the registration certificates for the medical devices produced.

The food and drug supervision and administration department that accepts the application for production license shall, within 30 working days after its acceptance, review the application materials and check them according to the requirements set forth in quality management standards for medical devices production by the food and drug supervision and administration department under the State Council. For the qualified medical devices, the license shall be approved and a medical device production license shall be issued; for the medical devices that fail to meet such conditions, the license shall be refused and written reasons shall be given.

The medical device production license is valid for five years. Where the period of validity for the license needs to be extended upon the expiration, the procedures for such extension shall be handled in accordance with the provisions of laws related to administrative licensing.

Article 23 Such matters that affect the safety [*17] and effectiveness of medical devices as the design and development, conditions for production equipment, purchasing of raw materials, control of production process of medical devices as well as institutional setup and personnel allocation of the enterprise shall be explicitly stipulated in the quality management standards for medical devices production.

Article 24 A medical device manufacturer shall, according to the requirements of the quality management standards for medical device production, set up and improve the quality management system that meets the needs of the medical devices produced and ensure the effective operation thereof; it shall, in strict accordance with the registered and record-filed technical requirements for products, organize the production to ensure that the manufactured medical devices comply with the compulsory standards and the registered and record-filed technical requirements therefor.

The medical device manufacturer shall regularly inspect the operation of the quality management system by itself and submit its self-inspection report to the food and drug supervision and administration department of the people's government in the province, autonomous [*18] region or municipality directly under the Central Government where the producing enterprise is located.

Article 25 Where any change in the production conditions of a medical device manufacturer causes a failure to meet the requirements of the quality management system for medical devices, the manufacturer shall adopt rectification measures immediately; where such change may affect the

safety and effectiveness of medical devices, the manufacturer shall immediately stop its production and report to the food and drug supervision and administration department of the people's government at county level where the manufacturer is located.

Article 26 Medical devices shall use general names. And the general name shall comply with the naming rules for medical devices formulated by the food and drug supervision and administration department under the State Council.

Article 27 Medical devices shall be attached with instructions and labels whose contents shall be consistent with those registered or record-filed.

The instructions and labels of medical devices shall indicate the following matters:

1. general name, model and specification;

2. name, domicile, production address and contact [*19] information of the producing enterprise;
3. serial number of the technical requirements for products;
4. production date and service life or expiration date;
5. product performance, main structure and applicable scope;
6. contraindications, points for attention and other contents necessary to be warned or reminded;
7. installation and operation instructions or drawings;
8. maintenance method and special storage condition and method; and
9. other contents that shall be stated as required by the technical requirements for products.

For Class II and Class III medical devices, number of the medical device registration certificate and the name, address and contact information of the registrant of the medical devices shall be also indicated.

For the medical devices used by the consumers independently, special instructions for safe use shall be also included.

Article 28 For the medical devices produced by entrust, the entrusting party shall be responsible for the quality of entrusted medical devices. The entrusted party shall be the medical device manufacturer that complies with the provisions hereof and has corresponding production conditions. The entrusting party shall strengthen the [*20] management of the production by the entrusted to ensure the production is conducted according to statutory requirements.

The implantable medical devices with high risk shall not be entrusted to produce. The specific contents shall be produced, adjusted and promulgated by the food and drug supervision and administration department under the State Council.

Chapter IV Operation and Use of Medical Devices

Article 29 To engage in the operation of medical devices, an operating enterprise shall have premises and storage conditions that match the business scale and scope, and have a quality management system and be equipped with quality management institutions or personnel that meet the needs of the operated medical devices.

Article 30 Where engaging in operation of Class II medical devices, an operating enterprise shall make a record-filing with the food and drug supervision and administration department of the people's government of the city divided into districts where the operating enterprise is located, and submit the supporting materials that meet the requirements of Article 29 hereof.

Article 31 Where engaging in operation of Class III medical devices, an operating enterprise [*21] shall apply to the food and drug supervision and administration department of the people's government of the city divided into districts where the operating enterprise is located for business license and submit the supporting materials that meet the requirements of Article 29 hereof.

The food and drug supervision and administration department that accepts the application for operation license shall, within 30 working days after its acceptance, review the application materials and organize an examination if necessary. For the medical devices that meet the conditions stipulated, the license shall be approved and a medical device operation license shall be granted; for the medical devices that fail to meet such conditions, the license shall be refused and written reasons shall be given.

The medical device operation license is valid for five years. Where the period of validity for the license needs to be extended upon the expiration, the procedures for such extension shall be handled in accordance with the provisions of laws related to administrative licensing.

Article 32 When the operating enterprises of medical devices or users purchase medical devices, they shall check the qualification [*22] of suppliers and the eligible supporting materials of medical devices and establish an entry inspection record system. The operating enterprises engaging in wholesale business of Class II and Class III medical devices and retail business of Class III medical devices shall establish a sales record system.

Matters to be recorded include:

1. name, model, specification and quantity of medical devices;

2. batch number, period of validity and sales date of medical devices;

3. name of the producing enterprise;

4. name, address and contact information of their supplier or purchaser; and

5. numbers of supporting documents of relevant license, etc.

The entry inspection record and sales record shall be real and be kept during the period specified by the food and drug supervision and administration department under the State Council. The state encourages the record by means of advanced technology.

Article 33 The transportation and storage of medical devices shall comply with the requirements of instructions and labels of medical devices; if there are special requirements on temperature, humidity and other environmental conditions, corresponding measures shall be taken to ensure the safety and [*23] effectiveness of medical devices.

Article 34 The users of medical devices shall have storage places and conditions that meet the needs of the varieties and quantities of the currently used medical devices. The users of medical devices

shall strengthen the technical training for their staff and instruct them to use the medical devices according to requirements in product specifications and technical operation standards.

The users of medical devices shall comply with the allocation plan on large-sized medical equipment formulated by the health and family planning department of the State Council when they are equipped with large-sized medical equipment, which shall match the functional orientation and the clinical service requirements. They shall possess corresponding technical conditions, supporting facilities and are staffed with professional technicians who have corresponding qualifications and ability, and be approved by the health and family planning departments of the people's governments above the provincial level, and have obtained license for allocation of large-sized medical equipment.

Administrative measures for large-sized medical equipment allocation shall be formulated [*24] by the health and family planning department of the State Council in concert with relevant departments of the State Council. The catalogue of large-sized medical equipment shall be proposed by the health and family planning department of the State Council in consultation with relevant departments of the State Council, and be implemented after approved by the State Council.

Article 35 The reused medical devices shall be handled by the users of medical devices in accordance with the provisions on sterilization and management stipulated by the competent health and family planning department of the State Council.

The disposable medical devices shall not be reused and the used ones shall be destroyed and recorded in accordance with the relevant provisions of the state.

Article 36 The users of medical devices shall, according to the requirements of product instructions, check, inspect, calibrate and maintain the medical devices that regularly need doing so and make records, timely analysis and evaluation to make sure the medical devices are in a good condition and to guarantee the quality in use; for large medical devices with long use life, files for use of such medical devices shall [*25] be established one by one and such matters as use, maintenance, transfer and actual use life shall be recorded. The retention period for records shall be no less than five years after the expiration of specified use life of medical devices.

Article 37 The users of medical devices shall carefully keep the source information of Class III medical devices purchased and ensure the traceability of such information.

Where large medical devices and implantable and interventional medical devices are used, such information as name and key technical parameters of medical devices and essential information closely related to quality and safety for use shall be recorded in medical history and other relevant records.

Article 38 Where any medical device in use is found to have potential safety hazards, the users of medical devices shall immediately stop to use it and require the producing enterprise or other institutions responsible for product quality to conduct examination and maintenance; if the medical device fails to meet the safety standards for use after the examination and maintenance, it shall no longer be used.

Article 39 The food and drug supervision and administration department [*26] and the competent health and family planning department shall exercise their respective duties to supervise and administer the quality and use of medical devices in use.

Article 40 The operating enterprise and user of medical devices shall not operate and use the expired, invalid and obsolete medical devices without eligible supporting materials that fail to be registered in accordance with the law.

Article 41 For transfer of medical devices in use between the users of medical devices, the transferor shall ensure the safety and effectiveness of the medical devices transferred, and no expired, invalid, obsolete and unqualified medical devices shall be transferred.

Article 42 Imported medical devices shall be those registered or record-filed in accordance with the provisions of Chapter II hereof.

Imported medical devices shall be attached with Chinese instructions and Chinese labels, which shall comply with the provisions hereof and requirements of the relevant compulsory standards. The instructions shall clearly indicate the origin of medical devices and name, address and contact information of the agent. Medical devices without Chinese instructions and Chinese labels or those [*27] whose instructions and labels do not comply with the provisions of this Article shall not be imported.

Article 43 Entry-exit inspection and quarantine institutions shall carry out inspection on imported medical devices in accordance with the law; where the medical devices are unqualified, they shall not be imported.

The food and drug supervision and administration department under the State Council shall timely report to the national entry-exit inspection and quarantine department the registration and record-filing of imported medical devices. The entry-exit inspection and quarantine institutions where the import port is located shall timely report to the food and drug supervision and administration department of the people's government of the city divided into districts where the import port is located the customs clearance of imported medical devices.

Article 44 An exporter of medical devices shall make sure that its exported medical devices meet the requirements of the importing country (region).

Article 45 The advertisement of medical devices shall be real and legal and shall not include any false, exaggerate and misleading contents.

Advertisement of medical devices shall [*28] be examined and approved by the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where the producing enterprise or the agent of imported medical devices is located. Approval documents for such advertisement shall be obtained. Where the advertiser publishes the advertisement of medical devices, it shall check the approval documents and the authenticity thereof in advance; no advertisement of medical devices with approval documents not obtained, authenticity thereof not proved or contents inconsistent with approval documents shall be published. The food and drug supervision and administration

department of the people's government in the province, autonomous region or municipality directly under the Central Government shall disclose and timely update the advertisement list of approved medical devices and approved advertising contents.

Where the food and drug supervision and administration department of the people's government at provincial level or above orders to suspend the production, sales, importing and use of the medical devices, no such medical devices shall [*29] be advertised during the period of suspension.

The examination measures for advertisement of medical devices shall be prepared by the food and drug supervision and administration department under the State Council in concert with the administrative department for industry and commerce under the State Council.

Chapter V Handling of Adverse Events and Recall of Medical Devices

Article 46 The state shall set up monitoring system for adverse events of medical devices to collect, analyze, evaluate and control such adverse events in a timely manner.

Article 47 The producing and operating enterprise or users shall monitor the adverse events of medical devices produced, operated or used by them; if any adverse event or suspicious event of medical devices is found, it shall be reported to the monitoring technical institutions of adverse events of medical devices in accordance with the provisions of the food and drug supervision and administration department under the State Council.

Any unit and individual who finds any adverse event or suspicious event of medical devices is entitled to report to the food and drug supervision and administration department or the monitoring technical institutions [*30] of adverse events of medical devices.

Article 48 The food and drug supervision and administration department under the State Council shall strengthen the construction of monitoring information network for adverse events of medical devices.

The monitoring technical institutions of adverse events of medical devices shall intensify the monitoring of adverse events of medical devices and actively collect the information of adverse events; if any adverse event is found or reported, the monitoring technical institutions shall timely check, investigate, analyze and evaluate the adverse event and propose to the food and drug supervision and administration department and the competent health and family planning department with handling suggestions.

The monitoring technical institutions of adverse events of medical devices shall make its contact information public for the convenience of reporting the adverse events of medical devices by the producing and operating enterprises or users.

Article 49 The food and drug supervision and administration department shall, according to the evaluation results of adverse events of medical devices, take such control measures as publishing warning information [*31] and ordering to suspend the production, sales, importing and use in a timely manner.

The food and drug supervision and administration department of the people's government at provincial level or above shall, in concert with the competent health and family planning department

and the relevant departments at the same level, organize a timely investigation on and deal with the adverse events of medical devices resulting in sudden serious damage or death, or serious damage to or death of masses, and strengthen the monitoring on the medical devices of the same kind.

Article 50 The producing and operating enterprises or users shall be cooperative in investigation of adverse events of medical devices carried out by the monitoring technical institutions of adverse events of medical devices and the food and drug supervision and administration department.

Article 51 The food and drug supervision and administration department of the people's government at provincial level or above shall reevaluate the registered and filed medical devices under any of the following circumstances:

1. there is any change in recognition of safety and effectiveness of medical devices with the development of scientific [*32] research;

2. the results of monitoring and evaluation of adverse events of medical devices state that the medical devices may have defects; and

3. other circumstances necessary for reevaluation stipulated by the food and drug supervision and administration department under the State Council.

Where the results of reevaluation suggest that safety and effectiveness of the registered medical devices cannot be guaranteed, the medical device registration certificate shall be cancelled by the original issuing department and such cancellation shall be published to the public. The medical devices with medical device registration certificate cancelled shall not be produced, imported, operated or used.

Article 52 Where a producing enterprise of medical devices finds that the medical devices produced by it do not meet the compulsory standards or registered or record-filed technical requirements for products or exist other defects, it shall immediately stop the production and require the relevant producing and operating enterprises, users and consumers to stop to operate and use such medical devices, recall the medical devices already sold on the market, take remedial measures or destroy such [*33] defective devices, record the relevant situation and release the relevant information, and report to the food and drug supervision and administration department and the competent health and family planning department the recall and handling of medical devices.

Where an operating enterprise of medical devices finds that the medical devices operated by it fall into any circumstance stated in the preceding paragraph, it shall immediately stop the operation, inform the relevant producing and operating enterprises, users and consumers and make the relevant records. Where the producing enterprise of medical devices thinks such devices fall into the category of those necessary for recall in accordance with the provisions of the preceding paragraph, such devices shall be immediately recalled.

Where a producing and operating enterprise fails to recall the medical devices or suspend its operation in accordance with the provisions of this Article, the food and drug supervision and administration department may order it to recall the medical devices or suspend its operation.

Chapter VI Supervision and Examination

Article 53 The food and drug supervision and administration department shall [*34] strengthen the supervision and examination on the registration, record-filing, production, operation and use, and focus the supervision and examination on the following matters:

1. whether the producing enterprise of medical devices organizes the production according to the registered or record-filed technical requirements for products;

2. whether the quality management system of the producing enterprise of medical devices keeps effective operation; and

3. whether the producing and operating conditions of the producing and operating enterprises of medical devices consistently meet the statutory requirements.

Article 54 During the supervision and examination, the food and drug supervision and administration department is entitled to:

1. conduct an inspection and a sampling on the site;

2. look up, copy, seal up or detain the relevant contracts, notes, account books and other relevant materials;

3. seal up or detain the medical devices that fail to meet the statutory requirements, illegally used spare and accessory parts and raw materials, and tools and equipment for illegally producing medical devices; and

4. seal up the places for production and operation of the medical devices [*35] in violation of the provisions hereof.

Where the food and drug supervision and administration department carries out supervision and examination, it shall show its law enforcement certificate and keep confidential of trade secrets of the examined unit.

The relevant units and individuals shall be cooperative in the supervision and examination by the food and drug supervision and administration department and shall not conceal any relevant issue.

Article 55 For medical devices that are harmful to human beings or are proved to probably jeopardize the health of human beings, the food and drug supervision and administration department may take urgent control measures as suspending production, importing, operation and use.

Article 56 The food and drug supervision and administration department shall reinforce the random inspections over the medical devices produced, operated and used by enterprises producing, operating and using them. No inspection fees or other expenses shall be charged for the random inspections, and the expenses required shall be included in the budget of government at the same level. The food and drug supervision and administration department of the people's government [*36] at the provincial level or above shall, according to the results of random inspections, publish the announcement on the quality of medical devices in a timely manner.

The health and family planning department shall carry out supervision and evaluation on the using conditions of large-sized medical equipment, and once discovering any improper operation, or situations such as excessive examination, excessive treatment, etc. that are relevant to large-sized medical equipment, the health and family planning department shall immediately correct them, and handle them in accordance with the law.

Article 57 Qualification identification by the medical device inspection institutions implements unified management in accordance with the relevant provisions of the state. Only the supervision and administration department certificated and recognized by the State Council may, in concert with the food and drug supervision and administration department under the State Council, inspect the medical devices.

Where the food and drug supervision and administration department needs to inspect the medical devices during the law enforcement, it shall entrust qualified medical device inspection institutions [*37] to do so and pay the relevant expenses.

Where the party concerned has any objection to the inspection conclusion, it may, within seven working days after receipt of it, select a qualified medical device inspection institution to re-inspect the devices. Such medical device inspection institution that conducts the re-inspection shall provide a conclusion within the time limit stipulated by the food and drug supervision and administration department under the State Council. The conclusion of the re-inspection shall be final.

Article 58 Where the medical devices that probably have hazardous substances or whose deign, raw materials and production process are changed without authorization and that have potential safety hazards cannot be inspected through inspection items and inspection methods specified in the national standards and industrial standards for medical devices, the medical device inspection institution may supplement inspection items and inspection methods to conduct the inspection; The inspection conclusion acquired by use of supplementary inspection items and inspection methods shall, upon approval of the food and drug supervision and administration department under the [*38] State Council, be the basis for identification of quality of medical devices by the food and drug supervision and administration department.

Article 59 The food and drug supervision and administration department of the people's government of the city divided into districts and at county level shall enhance the supervision and examination on the advertisement of medical devices; if finding any advertisement of medical devices that is disapproved or whose contents approved are falsified, it shall report to the food and drug supervision and administration department of the people's government in the province, autonomous region or municipality directly under the Central Government where it is located, and make such advertisement public.

The administrative department for industry and commerce shall, in accordance with the provisions of relevant laws and administrative regulations on administration over advertisements, supervise and examine the advertisement of medical devices and punish illegal acts. If the food and drug supervision and administration department finds any illegal release of advertisement of medical devices, it shall propose the handling suggestions and transfer the case [*39] according to the relevant procedures to the administrative department for industry and commerce at the same level where it is located.

Article 60 The food and drug supervision and administration department under the State Council shall establish a unified supervision and administration information platform for medical devices. The food and drug supervision and administration department shall timely disclose such daily supervision and administration information as license, record-filing, random inspection and punishment of illegal acts of medical devices on the information platform, but shall not reveal the trade secrets of the party concerned.

The food and drug supervision and administration department shall set up credit archives for registrants, record-filing persons of medical devices, producing and operating enterprises and users and conduct more supervision and examination on those with bad credit records.

Article 61 The food and drug supervision and administration department and other departments shall make public their contact information and accept the consultations, complaints and reporting. When the food and drug supervision and administration department and other departments [*40] are consulted on supervision and administration of medical devices, they shall give a reply in a timely manner; if receiving a complaint and reporting, they shall check and handle the complaint and reporting and give a reply in a timely manner. The information on consultations, complaints and reporting as well as the reply, check and handling shall be recorded and kept.

Where the reporting on research, production, operation and use of medical devices is investigated to be true, the food and drug supervision and administration department and other departments shall give an award to reporters.

Article 62 When the food and drug supervision and administration department under the State Council formulates, adjusts and revises the contents specified herein and specifications related to the supervision and administration over medical devices, it shall seek for public comments, and it shall, by means of hearing and discussion meetings or otherwise, listen to the opinions of experts, producing and operating enterprises and users of medical devices, consumers and the relevant organizations.

Chapter VII Legal Liabilities

Article 63 Under any of the following circumstances, the food and [*41] drug supervision and administration department of the people's government at county level or above shall confiscate illegal gains, the illegally produced and operated medical devices and tools, equipment, raw materials and other articles used for illegal production and operation; where the value of illegally produced and operated medical devices is less than CNY10,000, a fine of not less than CNY50,000 but not more than CNY100,000 shall be imposed; where the value is not less than CNY10,000, a fine of not less than ten times but not more than 20 times the value shall be imposed; where the circumstances are serious, the application for license of medical devices proposed by the relevant persons responsible and enterprises shall not be accepted within five years:

1. the enterprise produces and operates Class II and Class III medical devices without obtaining the medical device registration certificate;

2. the enterprise engages in the production of Class II and Class III medical devices without permission; and

3. the enterprise engages in the operation of Class III medical devices without permission.

Where the circumstance of Item 1 of the preceding paragraph occurs and the circumstance [*42] is serious, the original issuing department shall revoke the medical device production license or the medical device operation license.

Any person allocating and using large-sized medical equipment without permission shall be ordered by the health and family planning department at the county level or above to crease the use, given a warning, and its illegal gains be confiscated; and if the illegal gains are less than CNY10,000, a fine of not less than CNY10,000 but not more than CNY50,000 shall be imposed; and if the illegal gains

are more than CNY10,000, a fine of not less than five times but not more than ten times the illegal gains shall be imposed; where the circumstances are serious, the application for license for allocation of large-sized medical equipment filed by the relevant persons responsible and enterprises shall not be accepted within five years.

Article 64 In case the medical device registration certificate, medical device production license, medical device operation license, license for allocation of large-sized medical equipment, advertisement approval documents and other licenses have been obtained by providing false materials or through other deceptive means, [*43] the original issuing department shall revoke the license granted and impose a fine of not less than CNY50,000 but not more than CNY100,000, and the application for license of medical devices filed by the relevant persons responsible and enterprises shall not be accepted within five years.

In case the relevant medical device licenses are counterfeited, altered, traded, leased or lent, the original issuing department shall confiscate or revoke such licenses and confiscate illegal gains; in case the illegal gains are less than CNY10,000, a fine of not less than CNY10,000 but not more than CNY30,000 shall be imposed; in case the illegal gains are not less than CNY10,000, a fine of not less than three times but not more than five times the illegal gains shall be imposed; in case a violation of security administration is constituted, the public security organs shall impose a security administration punishment in accordance with the law.

Article 65 Where a record-filing fails to be made in accordance with the Regulations, the food and drug supervision and administration departments of the local people's governments at county level or above shall order to make corrections within the time [*44] limit; if corrections are not made within the time limit, the unit and names of products failing to be record-filed shall be made public and a fine of not more than CNY10, 000 shall be imposed.

Where false materials are provided in record-filing, the food and drug supervision and administration departments of the local people's governments at county level or above shall make public the unit and names of products to be record-filed; if the circumstance is serious, the person directly responsible shall not engage in the production and operation of medical devices with five years.

Article 66 Under any of the following circumstances, the food and drug supervision and administration department of the people's government at county level or above shall order to make corrections, confiscate the illegally produced, operated or used medical devices; where the value of illegally produced, operated or used medical devices is less than CNY10,000, a fine of not less than CNY20,000 but not more than CNY50,000 shall be imposed; where the value is not less than CNY10,000, a fine of not less than five times but not more than ten times the value shall be imposed; where the circumstances are serious, [*45] the food and drug supervision and administration department of the people's government at county level or above shall order to stop the production and operation and the original issuing department shall revoke the medical device registration certificate, medical device production license and medical device operation license:

1. the enterprise produces, operates or uses medical devices that do not comply with the compulsory standards or the registered or record-filed technical requirements for products;

2. the producing enterprise of medical devices fails to organize the production according to the registered or record-filed technical requirements for products; or to establish quality management system and keep effective operation in accordance with the provisions hereof;

3. the enterprise operates and uses the expired, invalid and obsolete medical devices without eligible supporting materials or uses those failing to be registered in accordance with the law;

4. the enterprise refuses to recall medical devices or stop the operation of medical devices after the food and drug supervision and administration department order it to recall medical devices or stop the operation of medical [*46] devices in accordance with the provisions hereof; and

5. the enterprise entrusts other enterprises without the conditions specified herein to produce medical devices or fails to manage the production by the entrusted.

If the operating enterprises or users of medical devices have fulfilled their incoming inspection and other obligations as stipulated by the Regulations, and have sufficient evidence to prove that they do not know that the medical devices that they operate or use are those stipulated in Items 1 and 3 of the preceding paragraph, and are able to truthfully state the sources of their purchase, they may be exempt from punishments, while the medical devices they operate and use that fail to meet the legal requirements shall be confiscated in accordance with law.

Article 67 Under any of the following circumstances, the food and drug supervision and administration department of the people's government at county level or above shall order to make corrections and impose a fine of not less than CNY10,000 but not more than CNY30,000; where the circumstances are serious, the food and drug supervision and administration department of the people's government at county level or above [*47] shall order to stop the production and operation and the original issuing department shall revoke the medical device production license and medical device operation license:

1. production conditions of the producing enterprise of medical devices have been changed and thus no longer meet the requirements of quality management system for medical devices but the producing enterprise fails to rectify the conditions and to stop the production and reporting in accordance with the Regulations;

2. production and operation instructions and labels do not comply with those for medical devices specified herein;

3. the enterprise fails to transport and store the medical devices according to the requirements of instructions and labels thereof; and

4. the enterprise transfers the expired, invalid, obsolete and unqualified medical devices in use.

Article 68 Under any of the following circumstances, the food and drug supervision and administration department and health and family planning department of the people's government at county level or above shall, according to their respective duties, order to make corrections and give a warning; where the enterprise refuses to make corrections, then a [*48] fine of not less than CNY5,000 but not more than CNY20,000 shall be imposed; where the circumstances are serious, the food and drug supervision and administration department and health and family planning department of the people's government at county level or above shall order to stop the production and operation and the original issuing department shall revoke the medical device production license and medical device operation license:

1. the producing enterprise of medical devices fails to submit the quality management system self-inspection report;

2. the operating enterprise and user of medical devices fail to establish and implement the entry inspection record system for medical devices in accordance with the provisions hereof;

3. the operating enterprise engaging in wholesale business of Class II and Class III medical devices and retail business of Class III medical devices fails to establish and implement the sales record system in accordance with the provisions hereof;

4. the user of medical devices fails to handle the reused medical devices in accordance with the provisions on sterilization and administration;

5. the user of medical devices reuses the disposable medical [*49] devices or fails to destroy the disposable medical devices that have been used in accordance with the provisions;

6. for medical devices that need regular check, inspection, calibration and maintenance, the user of medical devices fails to do so according to the requirements of the product instructions and to make records, timely analysis and evaluation so as to make sure the medical devices are in a good condition;

7. the user of medical devices fails to carefully keep the source materials of Class III medical devices purchased or fails to record the information on large medical devices and implantable and interventional medical devices in the medical history and other relevant records;

8. the user of medical devices that has found medical devices with potential safety hazards does not stop the use or ask for maintenance or continues to use the medical devices that are repaired but are not up to the safety use standards;

9. Where the user of medical devices uses large-sized medical equipment in violation of regulations, and fails to guarantee the medical quality and safety", and the original Item 9 is changed to be Item 10; and

10. the producing and operating enterprise and user [*50] of medical devices fail to monitor the adverse events of medical devices in accordance with the provisions hereof and to report the adverse events as required, or are not cooperative in investigation on the adverse events by the monitoring technical institutions of adverse events of medical devices and the food and drug supervision and administration department.

Article 69 Where an institution organizes clinical trials for medical devices in violation of the Regulations, the food and drug supervision and administration department of the people's government at the county level or above shall order it to make corrections or to immediately stop the clinical trials and may impose a fine of not more than CNY50,000; where a serious consequence is caused, such punishments as demotion, dismissal or discharge shall be imposed upon the directly responsible person and other persons directly liable; and this institution shall not carry out relevant professional clinical trials for medical devices within five years.

Where a clinical trial institution for medical devices issues a false report, a fine of not less than CNY50,000 but not more than CNY100,000 shall be imposed by the food and drug [*51] supervision and administration department of the people's government above the county level; illegal gains, if any, shall be confiscated; such punishments as dismissal or discharge shall be imposed upon the directly responsible person and other persons directly liable; this institution shall not carry out relevant professional clinical trials for medical devices within ten years.

Article 70 Where the inspection institutions of medical devices issue false inspection reports, the competent department that grants such qualifications shall cancel the inspection qualifications and shall not accept the application for qualification identification within ten years; a fine of not less than CNY50,000 but not more than CNY100,000 shall be imposed; illegal gains, if any, shall be confiscated; such punishments as dismissal or discharge shall be imposed upon the directly responsible person and other persons directly responsible; where the punishment of discharge is imposed, the inspection institutions shall not engage in the inspection of medical devices within ten years as of the date of such punishment.

Article 71 In violation of the provisions hereof, where the enterprise publishes the advertisement [*52] of medical devices whose approval documents are not obtained, publishes the advertisement of medical devices without proving the authenticity of the approval documents in advance or publishes the advertisement whose contents published are inconsistent with the approval documents, the administrative department for industry and commerce shall impose punishments in accordance with the provisions of the laws and administrative regulations on advertisement management.

Where the enterprise falsifies the contents of approved advertisement of medical devices, the original issuing department shall cancel the approval documents of such medical devices and shall not accept its applications for approval of advertisements within two years.

Where the enterprise publishes false advertisement of medical devices, the food and drug supervision and administration department of the people's government at county level or above shall decide to stop the sales of such medical devices and make it public; where the enterprise still sells such medical devices, the food and drug supervision and administration department of the people's government at county level or above shall confiscate the illegally sold medical [*53] devices and impose a fine of not less than CNY20,000 but not more than CNY50,000.

Article 72 Where technical evaluation institutions of medical devices and monitoring technical institutions of adverse events of medical devices, who fail to perform their duties in accordance with the provisions hereof, make major mistakes in the process of evaluation and monitoring, the food and drug supervision and administration department of the people's government at county level or above shall order them to make corrections, circulate a note of criticism and give a warning; where serious consequences have been caused, such punishments as degradation, dismissal or discharge shall be imposed on the directly responsible person and other persons directly responsible in accordance with the law.

Article 73 The food and drug supervision and administration departments, the health and family planning departments and the staff thereof shall, in strict accordance with the types and range of punishments specified herein and based on the nature of violations and specific circumstances, exercise the power of administrative penalty. Specific measures shall be formulated by the food and drug supervision and [*54] administration department and the health and family planning department under the State Council according to their respective duties.

Article 74 In violation of the provisions hereof, the food and drug supervision and administration department of the people's government at county level or above or other relevant departments do not perform their duties of supervision and administration over medical devices or misuse their authority, neglect their duties or practice graft, the supervision organ or the department in charge of appointment and removal shall give a warning, record a demerit or record a serious demerit on the

directly responsible person and other persons directly responsible; where serious consequences have been caused, such punishments as degradation, dismissal or discharge shall be imposed in accordance with the law.

Article 75 In violation of the provisions hereof, where a crime has been constituted, criminal liability shall be pursued in accordance with the law; where any damage to person or property or other damages have been caused, the

compensation liabilities shall be assumed in accordance with the law.

Chapter VIII Supplementary Provisions

Article 76 Definitions [*55] of the following terms herein:

Medical devices refer to instruments, equipment, appliances, in-vitro diagnostic reagents and calibrators, materials as well as other similar or relevant articles, including necessary computer software; the utility of medical devices is mainly achieved by physical or other means instead of by means of pharmacology, immunology or metabolism or by such means but only acting as auxiliary functions, the purposes of which are as follows:

1. diagnose, prevention, monitoring, treatment or relief on diseases;

2. diagnose, monitoring, treatment, relief or functional compensation on injury;

3. inspection on, substitution for, adjustment to or support of physical structures or physical process;

4. support or maintenance of life;

5. control of pregnancy; and

6. inspection on sample of human body to provide information for medical treatment or diagnosis.

The user of medical devices refers to the institutions that use medical devices to provide medical treatment and other technical services, including the medical institutions that have obtained the Practicing License of Medical Institutions, family planning technical service institutions that have obtained the Practicing [*56] License of Family Planning Technical Service Institutions and blood stations, blood plasma stations and assistive product adaption institutions that do not need to have Practicing License of Medical Institutions.

Large-sized medical equipment refer to the large-sized medical devices with complicated using technique, large-scale capital investment, and high operation costs, which would have a great influence on medical fees and which are subject to the catalogue management.

Article 77 Fees for registration of medical devices may be charged. Specific charging items and standards shall be worked out respectively by the competent financial and pricing departments under the State Council in accordance with relevant provisions of the state.

Article 78 Administrative measures for non-profit contraceptive medical devices and administrative measures of medical sanitation institutions for medical devices researched to response to public health emergencies shall be prepared by the food and drug supervision and administration department under the State Council in concert with the competent health and family planning department of the State Council.

Administrative measures for traditional [*57] Chinese medical devices shall be prepared by the food and drug supervision and administration department under the State Council in concert with the traditional Chinese medicine administration department under the State Council in accordance with the relevant provisions hereof; the scope of assistive medical devices and administrative measures thereof shall be prepared by the food and drug supervision and administration department under the State Council in concert with the civil administration department under the State Council in accordance with the provisions hereof.

Article 79 The supervision and administration over use of military medical devices shall be organized and implemented by the competent military health department in accordance with the Regulations and the relevant military provisions.

Article 80 The Regulations shall come into force as of June 1, 2014.

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